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(54) Title: VESSEL SEALER AND DIVIDER AND METHOD OF MANUFACTURING SAME

(57) Abstract: A bipolar forceps includes a shaft having opposing jaw members at a distal end thereof and a drive assembly for moving the jaw members relative to one another from a first position wherein the jaw members are disposed in spaced relation relative to one another to a second position wherein the jaw members cooperate to grasp tissue therebetween. The forceps also includes a handle having a first and second gripping portions which cooperate with first and second movable actuators, respectively, for independently actuating the drive assembly to move the jaw members. The forceps is connected to source of electrical energy such that the jaw members are capable of conducting energy through tissue held therebetween to effect a tissue seal. The forceps also includes a selectively advanceable knife assembly for cutting tissue along the tissue seal.

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VESSEL SEALER AND DIVIDER AND METHOD OF MANUFACTURING SAME

CROSS REFERENCE TO RELATED APPLICATION:

This application is a continuation-in-part of U.S. Application Serial No. 10/179,863 filed on June 25, 2002 by Dycus, et al. entitled "VESSEL SEALER AND DIVIDER" which is a continuation-in-part of U.S. Application Serial No. 10/116,944 filed on May 16, 2002 by Dycus, et al. entitled "VESSEL SEALER AND DIVIDER" which is a continuation-in-part of PCT Application Serial No. PCT/US02/01890 filed on January 25, 2002 by Dycus, et al. entitled "VESSEL SEALER AND DIVIDER" which is a continuation-in-part of PCT Application Serial No. PCT/US01/11340 filed on April 6, 2001 by Dycus, et al. entitled "VESSEL SEALER AND DIVIDER", the entire contents of all of these applications are hereby incorporated by reference herein.

BACKGROUND

The present disclosure relates to an electrosurgical instrument and method for performing endoscopic surgical procedures and more particularly, the present disclosure relates to an open or endoscopic bipolar electrosurgical forceps and method for sealing and/or cutting tissue.

Technical Field

A hemostat or forceps is a simple plier-like tool which uses mechanical action between its jaws to constrict vessels and is commonly used in open surgical procedures to grasp, dissect and/or clamp tissue. Electrosurgical forceps utilize both mechanical clamping action and electrical energy to effect hemostasis by heating the tissue and blood vessels to coagulate, cauterize and/or seal tissue.

Over the last several decades, more and more surgeons are complimenting traditional open methods of gaining access to vital organs and

body cavities with endoscopes and endoscopic instruments which access organs through small puncture-like incisions. Endoscopic instruments are inserted into the patient through a cannula, or port, that has been made with a trocar. Typical sizes for cannulas range from three millimeters to twelve millimeters. Smaller cannulas are usually preferred, which, as can be appreciated, ultimately presents a design challenge to instrument manufacturers who must find ways to make surgical instruments that fit through the cannulas.

Certain endoscopic surgical procedures require cutting blood vessels or vascular tissue. However, due to space limitations surgeons can have difficulty suturing vessels or performing other traditional methods of controlling bleeding, e.g., clamping and/or tying-off transected blood vessels. Blood vessels, in the range below two millimeters in diameter, can often be closed using standard electrosurgical techniques. However, if a larger vessel is severed, it may be necessary for the surgeon to convert the endoscopic procedure into an open-surgical procedure and thereby abandon the benefits of laparoscopy.

Several journal articles have disclosed methods for sealing small blood vessels using electrosurgery. An article entitled Studies on Coagulation and the Development of an Automatic Computerized Bipolar Coagulator, J. Neurosurg., Volume 75, July 1991, describes a bipolar coagulator which is used to seal small blood vessels. The article states that it is not possible to safely coagulate arteries with a diameter larger than 2 to 2.5 mm. A second article is entitled Automatically Controlled Bipolar Electrocoagulation – "COA-COMP", Neurosurg. Rev. (1984), pp.187-190, describes a method for terminating electrosurgical power to the vessel so that charring of the vessel walls can be avoided.

As mentioned above, by utilizing an electrosurgical forceps, a surgeon can either cauterize, coagulate/desiccate and/or simply reduce or slow bleeding, by controlling the intensity, frequency and duration of the electrosurgical energy applied through the jaw members to the tissue. The electrode of each jaw member is charged to a different electric potential such that when the jaw members grasp tissue, electrical energy can be selectively transferred through the tissue.

In order to effect a proper seal with larger vessels, two predominant mechanical parameters must be accurately controlled - the pressure applied to the vessel and the gap distance between the electrodes - both of which are affected by the thickness of the sealed vessel. More particularly, accurate application of pressure is important to oppose the walls of the vessel; to reduce the tissue impedance to a low enough value that allows enough electrosurgical energy through the tissue; to overcome the forces of expansion during tissue heating; and to contribute to the end tissue thickness which is an indication of a good seal. It has been determined that a typical fused vessel wall is optimum between 0.001 and 0.005 inches. Below this range, the seal may shred or tear and above this range the lumens may not be properly or effectively sealed.

With respect to smaller vessel, the pressure applied to the tissue tends to become less relevant whereas the gap distance between the electrically conductive surfaces becomes more significant for effective sealing. In other words, the chances of the two electrically conductive surfaces touching during activation increases as the vessels become smaller.

Electrosurgical methods may be able to seal larger vessels using an appropriate electrosurgical power curve, coupled with an instrument capable of applying a large closure force to the vessel walls. It is thought that the process of coagulating small vessels is fundamentally different than electrosurgical vessel sealing. For the purposes herein, "coagulation" is defined as a process of desiccating tissue wherein the tissue cells are ruptured and dried. Vessel sealing is defined as the process of liquefying the collagen in the tissue so that it reforms into a fused mass. Thus, coagulation of small vessels is sufficient to permanently close them. Larger vessels need to be sealed to assure permanent closure.

U.S. Patent No. 2,176,479 to Willis, U.S. Patent Nos. 4,005,714 and 4,031,898 to Hiltebrandt, U.S. Patent Nos. 5,827,274, 5,290,287 and 5,312,433 to Boebel et al., U.S. Patent Nos. 4,370,980, 4,552,143, 5,026,370 and 5,116,332 to Lottick, U.S. Patent No. 5,443,463 to Stern et al., U.S. Patent No. 5,484,436 to Eggers et al. and U.S. Patent No. 5,951,549 to Richardson et al., all relate to electrosurgical instruments for coagulating, cutting and/or sealing vessels or tissue. However, some of these designs may not provide

uniformly reproducible pressure to the blood vessel and may result in an ineffective or non-uniform seal.

Many of these instruments include blade members or shearing members which simply cut tissue in a mechanical and/or electromechanical manner and are relatively ineffective for vessel sealing purposes. Other instruments rely on clamping pressure alone to procure proper sealing thickness and are not designed to take into account gap tolerances and/or parallelism and flatness requirements which are parameters which, if properly controlled, can assure a consistent and effective tissue seal. For example, it is known that it is difficult to adequately control thickness of the resulting sealed tissue by controlling clamping pressure alone for either of two reasons: 1) if too much force is applied, there is a possibility that the two poles will touch and energy will not be transferred through the tissue resulting in an ineffective seal; or 2) if too low a force is applied the tissue may pre-maturely move prior to activation and sealing and/or a thicker, less reliable seal may be created.

As mentioned above, in order to properly and effectively seal larger vessels, a greater closure force between opposing jaw members is required. It is known that a large closure force between the jaws typically requires a large moment about the pivot for each jaw. This presents a challenge because the jaw members are typically affixed with pins which are positioned to have a small moment arms with respect to the pivot of each jaw member. A large force, coupled with a small moment arm, is undesirable because the large forces may shear the pins. As a result, designers must compensate for these large closure forces by either designing instruments with metal pins and/or by designing instruments which at least partially offload these closure forces to reduce the chances of mechanical failure. As can be appreciated, if metal pivot pins are employed, the metal pins must be insulated to avoid the pin acting as an alternate current path between the jaw members which may prove detrimental to effective sealing.

Increasing the closure forces between electrodes may have other undesirable effects, e.g., it may cause the opposing electrodes to come into close contact with one another which may result in a short circuit and a small closure force may cause pre-mature movement of the issue during compression

and prior to activation. As a result thereof, providing an instrument which consistently provides the appropriate closure force between opposing electrode within a preferred pressure range will enhance the chances of a successful seal. As can be appreciated, relying on a surgeon to manually provide the appropriate closure force within the appropriate range on a consistent basis would be difficult and the resultant effectiveness and quality of the seal may vary. Moreover, the overall success of creating an effective tissue seal is greatly reliant upon the user's expertise, vision, dexterity, and experience in judging the appropriate closure force to uniformly, consistently and effectively seal the vessel. In other words, the success of the seal would greatly depend upon the ultimate skill of the surgeon rather than the efficiency of the instrument.

It has been found that the pressure range for assuring a consistent and effective seal is between about 3 kg/cm^2 to about 16 kg/cm^2 and, preferably, within a working range of 7 kg/cm^2 to 13 kg/cm^2. Manufacturing an instrument which is capable of providing a closure pressure within this working range has been shown to be effective for sealing arteries and other vascular bundles.

Various force-actuating assemblies have been developed in the past for providing the appropriate closure forces to effect vessel sealing. For example, one such actuating assembly has been developed by Valleylab Inc., a division of Tyco Healthcare LP for use with Valleylab's vessel sealing and dividing instrument commonly sold under the trademark LIGASURE ATLAS®. This assembly includes a four-bar mechanical linkage, a spring and a drive assembly which cooperate to consistently provide and maintain tissue pressures within the above working ranges.

During assembly, it would be desirable to test the closure pressure between sealing surfaces to assure that the closure pressure falls within the preferred pressure range for sealing tissue and vascular bundles. Unfortunately, it has been found that measuring the closure pressure between the sealing surfaces is particularly difficult. For example, one of the inherent difficulties of accurately measuring the closure force includes measuring the closure force in a non-destructive fashion, i.e., placing a measuring device, such as a strain gauge or pressure sensitive film, between the jaw members interferes with the final angle of the jaw members, interfering with the

measurement. The measurement device would need to be shaped exactly like the jaw profile in order to measure the pressure accurately. The jaw would have to be free of stop members or only the peaks in pressure would be measured. Moreover, it has been found that manufacturing tolerances of the internal working components of the handle assembly and actuating assemblies may affect the overall closure pressure between the sealing surfaces.

Thus there exists a need to develop a reliable method for verifying that the closure pressure is within a preferred working range between sealing surfaces to effect a proper tissue seal.

During a given surgical procedure, one difficulty that may often arise for a surgeon is that the instrument may become somewhat unwieldy, cumbersome and/or difficult to actuate in a given position, i.e., the trigger may be positioned in an awkward position and difficult to grasp. For example, during an endoscopic surgical procedure where the cannula channel has a vertical axis, a surgeon may not be able to easily manipulate a pistol-type instrument and actuate the trigger without inadvertently changing the desired position (or angle) of the tool assembly or end effectors.

Accordingly, there exists a need to develop a surgical instrument which includes a plurality of spaced actuators for selectively operating the instrument in multiple orientations.

SUMMARY

The present disclosure relates to a bipolar forceps which includes a shaft having opposing jaw members at a distal end thereof and a drive assembly for moving the jaw members relative to one another from a first position wherein the jaw members are disposed in spaced relation relative to one another to a second position wherein the jaw members cooperate to grasp tissue therebetween. The forceps also includes a handle having a first and second gripping portions which cooperate with first and second movable actuators, respectively, for independently actuating the drive assembly to move the jaw members. The forceps is connected to source of electrical energy such that the jaw members are capable of conducting energy through tissue held therebetween to effect a tissue seal. The forceps also includes a selectively

advanceable knife assembly for cutting tissue along the tissue seal. Holding the forceps in a first position facilitates activation of the first movable actuator and holding the forceps in a second position facilitates activation of the second movable actuator.

Preferably, the forceps includes a first trigger for advancing the knife assembly when the forceps is held in the first position and a second trigger for advancing the knife assembly when the forceps is held in the second position. First and second deformable thumb rests may also be included to facilitate handling the forceps when the forceps is held in the first and second positions, respectively. The thumb rests may also be selectively removable and/or attachable from the forceps.

A rotating assembly may also be included for rotating the jaw members about a longitudinal axis defined through the shaft. In addition, at least one link member may be included to connect the first and second movable actuators to effect optional movement of the drive assembly and jaw members from either the first or second positions.

The present disclosure also relates to a method for verifying the closure pressure between jaw members of a forceps. The method includes the steps of: specifying a desired closure pressure range for effective tissue sealing; manufacturing each jaw member such that specifications of each jaw member fall within an acceptable manufacturing range, the specifications being selected from the group consisting of: surface area of each jaw member, distance from a pivot of each jaw member to a centroid of a sealing surface of each jaw member; angle between a cam slot of each jaw member and a line perpendicular to the sealing surface of each jaw member; distance from the cam slot to the pivot of each jaw member; and a width of the cam slot of each jaw member; providing a spring with a known spring constant and a known free length; activating the forceps the engage tissue; and measuring the compressed length of the spring to verify that the closure pressure falls within specified range.

BRIEF DESCRIPTION OF THE DRAWINGS

Various embodiments of the subject instrument are described herein with reference to the drawings wherein:

Fig. 1A is a left, perspective view of an endoscopic bipolar forceps showing a housing, a shaft and an end effector assembly according to the present disclosure;

Fig. 1B is a left, perspective of an open bipolar forceps according to the present disclosure;

Fig. 2 is a top view of the forceps of Fig. 1;

Fig. 3 is a right, side view of the forceps of Fig. 1;

Fig. 4 is a right, perspective view of the forceps of Fig. 1 showing the rotation of the end effector assembly about a longitudinal axis "A";

Fig. 5 is a front view of the forceps of Fig. 1;

Figs. 6 is an enlarged view of the indicated area of detail of Fig. 5 showing an enhanced view of the end effector assembly detailing a pair of opposing jaw members;

Fig. 7 is an enlarged, left perspective view of the indicated area of detail of Fig. 1 showing another enhanced view of the end effector assembly;

Fig. 8 is an enlarged, right side view of the indicated area of detail of Fig. 3 with a pair of cam slots of the end effector assembly shown in phantom;

Fig. 9 is a slightly-enlarged, cross-section of the forceps of Fig. 3 showing the internal working components of the housing;

Fig. 10 is an enlarged, cross-section of the indicated area of detail of Fig. 9 showing the initial position of a knife assembly disposed within the end effector assembly;

Fig. 11 is an enlarged, left perspective view showing the housing without a cover plate and the internal working components of the forceps disposed therein;

Fig. 12 is an exploded, perspective view of the end effector assembly, the knife assembly and the shaft;

Fig. 13. is an exploded, perspective view of the housing and the internal working components thereof with the attachment of the shaft and end effector assembly to the housing shown in broken line illustration;

Fig. 14 is greatly-enlarged, top perspective view of the end effector assembly with parts separated showing a feed path for an electrical cable through the top jaw member;

Fig. 15 is a longitudinal, cross-section of the indicated area of detail of Fig. 9;

Fig. 16 is an enlarged, top perspective view of the end effector assembly showing the feed path for the electrical cable through the opposing jaw members and the proximal attachment of the knife assembly to a longitudinally-reciprocating knife tube disposed within the shaft;

Fig. 17 is an enlarged, top perspective view of the end effector assembly showing the feed path for the electrical cable along a longitudinally-disposed channel defined within the outer periphery of the shaft;

Fig. 18A is a greatly-enlarged, side perspective view of the housing without the cover plate showing the feed path for the electrical cable through a rotating assembly adjacent to a distal end of the housing;

Fig. 18B is a greatly-enlarged, side perspective view of the housing without the cover plate showing the feed path for the electrical cable through a rotating assembly with the shaft mounted within the housing;

Fig. 19 is a greatly-enlarged, rear view of the rotating assembly showing an internally-disposed stop member;

Fig. 20 is a perspective view of the forceps of the present disclosure shown in position to grasp and seal a tubular vessel or bundle through a cannula;

Fig. 21 is a slightly-enlarged, cross-section of the internal, cooperative movements of a four-bar handle assembly disposed within the housing which effects movement of the jaw members relative to one another;

Fig. 22 is a greatly-enlarged, cross-section showing the initial movement of a flange upon activation of the four-bar handle assembly shown in phantom illustration;

Fig. 23 is a greatly-enlarged, side view showing the resulting compression movement of a coil spring in reaction to the movement of the four-bar handle assembly;

Fig. 24 is a greatly-enlarged, side view showing the proximal movement of a cam-like drive pin of the end effector assembly as a result of the proximal compression of the coil spring of Fig. 23 which, in turn, moves the opposing jaw members into a closed configuration;

Fig. 25 is a greatly-enlarged, cross-section showing the knife assembly poised for activation within a cannula;

Fig. 26 is a top perspective view showing the opposing jaw members in closed configuration with a tubular vessel compressed therebetween;

Fig. 27 is an enlarged perspective view of a sealed site of a tubular vessel showing a preferred cutting line "B-B" for dividing the tubular vessel after sealing;

Fig. 28 is a longitudinal cross-section of the sealed site taken along line 28-28 of Fig. 27;

Fig. 29 is a side view of the housing without a cover plate showing the longitudinal reciprocation of the knife tube upon activation of a trigger assembly;

Fig. 30 is a greatly-enlarged, cross-section of the distal end of the instrument showing longitudinal reciprocation of the knife assembly upon activation of the trigger assembly;

Fig. 31 is a longitudinal cross-section of the tubular vessel after reciprocation of the knife assembly through the sealing site along preferred cutting line "B-B" of Fig. 28;

Fig. 32 is a greatly-enlarged, side view showing movement of the flange upon re-initiation of the handle assembly along a predefined exit path which, in turn, opens the opposing jaw members and releases the tubular vessel;

Fig. 33 is a greatly enlarged, perspective view showing one particular stop member configuration on one of the vessel sealing surfaces of one of the jaw members;

Fig. 34A is an internal side view of the housing showing one embodiment of a handswitch for use with the present disclosure;

Fig. 34B is a schematic illustration of an alternate embodiment of the handswitch according to the present disclosure; and

Fig. 34C is a schematic illustration of another embodiment of the handswitch according to the present disclosure;

Figs. 35A and 35B are schematic illustrations of heating blocks according to the present disclosure;

Figs. 35C and 35D are schematic illustrations jaw members with intermittent sealing surface patterns;

Fig. 36 shows one embodiment of a slide tube cutter in accordance with the present invention;

Fig. 37A shows one embodiment of a laparoscopic forceps with the slide tube cutter of Fig. 36 wherein the slide tube cutter is poised for longitudinal reciprocation of U-shaped notched blade through a vessel along a seal plane "B-B";

Fig. 37B shows another embodiment of a laparoscopic forceps with the slide tube cutter of Fig. 36 wherein the slide tube cutter is poised for longitudinal reciprocation and rotation of U-shaped notched blade through a vessel along a seal plane "B-B";

Figs. 38A and 38B show tow alternate embodiments of the slide tube cutter in accordance with the present disclosure;

Fig. 39A shows a laparoscopic forceps having a unilateral closure mechanism shown in open configuration;

Fig. 39B shows a laparoscopic forceps having a unilateral closure mechanism shown in closed configuration;

Fig. 39C shows a laparoscopic forceps having a unilateral closure mechanism shown in open configuration with a knife blade and corresponding knife channel shown in phantom;

Fig. 39D shows a laparoscopic forceps having a unilateral closure mechanism shown in closed configuration with a knife blade and corresponding knife channel shown in phantom;

Fig. 40A shows a schematic representation of an alternate embodiment of the forceps according to the present disclosure with two movable actuators;

Fig. 40B shows an internal schematic view of a forceps similar to the forceps of Fig. 40A with a dual-actuator design; and

Fig. 41 shows a schematic view of the various parameters of the jaw members which should be accurately controlled to simply the measurement of the closure pressure.

DETAILED DESCRIPTION

Referring now to Figs. 1-6, one embodiment of a bipolar forceps 10 is shown for use with various surgical procedures and generally includes a housing 20, a handle assembly 30, a rotating assembly 80, a trigger assembly 70 and an end effector assembly 100 which mutually cooperate to grasp, seal and divide tubular vessels and vascular tissue 420 (Fig. 20). Although the majority of the figure drawings depict a bipolar forceps 10 for use in connection with endoscopic surgical procedures, an open forceps 10' is also contemplated for use in connection with traditional open surgical procedures and is shown by way of example in Fig. 1A. For the purposes herein, the endoscopic version is discussed in detail, however, it is contemplated that open forceps 10' also includes the same or similar operating components and features as described below.

More particularly, forceps 10 includes a shaft 12 which has a distal end 14 dimensioned to mechanically engage the end effector assembly 100 and a proximal end 16 which mechanically engages the housing 20. Preferably, shaft 12 is bifurcated at the distal end 14 thereof to form ends 14a and 14b which are dimensioned to receive the end effector assembly 100 as best seen in Figs. 7 and 12. The proximal end 16 of shaft 12 includes notches 17a (See Figs. 23 and 29) and 17b (See Figs. 11, 12 and 13) which are dimensioned to mechanically engage corresponding detents 83a (Fig. 18A) and 83b (Fig. 13 shown in phantom) of rotating assembly 80 as described in more detail below. In the drawings and in the descriptions which follow, the term "proximal", as is traditional, will refer to the end of the forceps 10 which is closer to the user, while the term "distal" will refer to the end which is further from the user.

As best seen in Fig. 1A, forceps 10 also includes an electrical interface or plug 300 which connects the forceps 10 to a source of electrosurgical energy, e.g., a generator (not shown). Preferably, generators such as those sold by Valleylab - a division of Tyco Healthcare LP, located in Boulder Colorado are used as a source of electrosurgical energy, e.g., FORCE EZ™ Electrosurgical Generator, FORCE FX™ Electrosurgical Generator, FORCE 1C™, FORCE 2™ Generator, SurgiStat™ II. One such system is described in

commonly-owned U.S. Patent No. 6,033,399 entitled "ELECTROSURGICAL GENERATOR WITH ADAPTIVE POWER CONTROL" the entire contents of which are hereby incorporated by reference herein. Other systems have been described in commonly-owned U.S. Patent No. 6,187,003 entitled "BIPOLAR ELECTROSURGICAL INSTRUMENT FOR SEALING VESSELS" the entire contents of which is also incorporated by reference herein.

Preferably, the generator includes various safety and performance features including isolated output, independent activation of accessories, and the Valleylab REM™ Contact Quality Monitoring System, which may substantially reduces the risk of burns under the patient return electrode. Preferably, the electrosurgical generator includes Valleylab's Instant Response™ technology features which provides an advanced feedback system which senses changes in tissue 200 times per second and adjusts voltage and current to maintain appropriate power. The Instant Response™ technology is believed to provide one or more of the following benefits to surgical procedure:

- Consistent clinical effect through all tissue types.
- Reduced thermal spread and risk of collateral tissue damage.
- Less need to "turn up the generator".
- Designed for the minimally invasive environment

Plug 300 includes a pair of prong members 302a and 302b which are dimensioned to mechanically and electrically connect the forceps 10 to the source of electrosurgical energy. An electrical cable 310 extends from the plug 300 to a sleeve 99 which securely connects the cable 310 to the forceps 10. As best seen in Figs. 9, 11 and 18A, cable 310 is internally divided into cable lead 310a and 310b which each transmit electrosurgical energy through their respective feed paths through the forceps 10 to the end effector assembly 100 as explained in more detail below.

Handle assembly 30 includes a fixed handle 50 and a movable handle 40. Fixed handle 50 is integrally associated with housing 20 and handle 40 is movable relative to fixed handle 50 as explained in more detail below with respect to the operation of the forceps 10. Rotating assembly 80 is preferably

attached to a distal end 303 (Fig. 18A) of housing 20 and is rotatable approximately 180 degrees in either direction about a longitudinal axis "A".

As best seen in Figs. 2 and 13, housing 20 is formed from two (2) housing halves 20a and 20b which each include a plurality of interfaces 307a, 307b and 307c (Fig. 13) which are dimensioned to mechanically align and engage one another to form housing 20 and enclose the internal working components of forceps 10. As can be appreciated, fixed handle 50 which, as mentioned above is integrally associated with housing 20, takes shape upon the assembly of the housing halves 20a and 20b.

It is envisioned that a plurality of additional interfaces (not shown) may disposed at various points around the periphery of housing halves 20a and 20b for ultrasonic welding purposes, e.g., energy direction/deflection points. It is also contemplated that housing halves 20a and 20b (as well as the other components described below) may be assembled together in any fashion known in the art. For example, alignment pins, snap-like interfaces, tongue and groove interfaces, locking tabs, adhesive ports, etc. may all be utilized either alone or in combination for assembly purposes.

Likewise, rotating assembly 80 includes two halves 80a and 80b which, when assembled, enclose and engage the proximal end 16 of shaft 12 to permit selective rotation of the end effector assembly 100 as needed. Half 80a includes a pair of detents 89a (Fig. 13) which are dimensioned to engage a pair of corresponding sockets 89b (shown in phantom in Fig. 13) disposed within half 80b. Movable handle 40 and trigger assembly 70 are preferably of unitary construction and are operatively connected to the housing 20 and the fixed handle 50 during the assembly process.

As mentioned above, end effector assembly 100 is attached to the distal end 14 of shaft 12 and includes a pair of opposing jaw members 110 and 120. Movable handle 40 of handle assembly 30 is ultimately connected to a drive rod 32 which, together, mechanically cooperate to impart movement of the jaw members 110 and 120 from an open position wherein the jaw members 110 and 120 are disposed in spaced relation relative to one another, to a clamping or closed position wherein the jaw members 110 and 120 cooperate to grasp

tissue 420 (Fig. 20) therebetween. This is explained in more detail below with respect to Figs. 9 -11 and 20-29.

It is envisioned that the forceps 10 may be designed such that it is fully or partially disposable depending upon a particular purpose or to achieve a particular result. For example, end effector assembly 100 may be selectively and releasably engageable with the distal end 14 of the shaft 12 and/or the proximal end 16 of shaft 12 may be selectively and releasably engageable with the housing 20 and the handle assembly 30. In either of these two instances, the forceps 10 would be considered "partially disposable" or "reposable", i.e., a new or different end effector assembly 100 (or end effector assembly 100 and shaft 12) selectively replaces the old end effector assembly 100 as needed.

Turning now to the more detailed features of the present disclosure as described with respect to Figs 1A - 13, movable handle 40 includes an aperture 42 defined therethrough which enables a user to grasp and move the handle 40 relative to the fixed handle 50. Handle 40 also includes an ergonomically-enhanced gripping element 45 disposed along the inner peripheral edge of aperture 42 which is designed to facilitate gripping of the movable handle 40 during activation. It is envisioned that gripping element 45 may include one or more protuberances, scallops and/or ribs 43a, 43b and 43c, respectively, to facilitate gripping of handle 40. As best seen in Fig. 11, movable handle 40 is selectively moveable about a pivot 69 from a first position relative to fixed handle 50 to a second position in closer proximity to the fixed handle 50 which, as explained below, imparts movement of the jaw members 110 and 120 relative to one another.

As shown best in Fig. 11, housing 20 encloses a drive assembly 21 which cooperates with the movable handle 40 to impart movement of the jaw members 110 and 120 from an open position wherein the jaw members 110 and 120 are disposed in spaced relation relative to one another, to a clamping or closed position wherein the jaw members 110 and 120 cooperate to grasp tissue therebetween. The handle assembly 30 can generally be characterized as a four-bar mechanical linkage composed of the following elements: movable handle 40, a link 65, a cam-like link 36 and a base link embodied by fixed handle 50 and a pair of pivot points 37 and 67b. Movement of the handle 40

activates the four-bar linkage which, in turn, actuates the drive assembly 21 for imparting movement of the opposing jaw members 110 and 120 relative to one another to grasp tissue therebetween. It is envisioned that employing a four-bar mechanical linkage will enable the user to gain a significant mechanical advantage when compressing the jaw members 110 and 120 against the tissue 420 as explained in further detail below with respect the operating parameters of the drive assembly 21. Although shown as a four-bar mechanical linkage, the present disclosure contemplates other linkages to effect relative motion of the jaw members 110 and 120 as is known in the art.

Preferably, fixed handle 50 includes a channel 54 defined therein which is dimensioned to receive a flange 92 which extends proximally from movable handle 40. Preferably, flange 92 includes a fixed end 90 which is affixed to movable handle 40 and a t-shaped free end 93 which is dimensioned for facile reception within channel 54 of handle 50. It is envisioned that flange 92 may be dimensioned to allow a user to selectively, progressively and/or incrementally move jaw members 110 and 120 relative to one another from the open to closed positions. For example, it is also contemplated that flange 92 may include a ratchet-like interface which lockingly engages the movable handle 40 and, therefore, jaw members 110 and 120 at selective, incremental positions relative to one another depending upon a particular purpose. Other mechanisms may also be employed to control and/or limit the movement of handle 40 relative to handle 50 (and jaw members 110 and 120) such as, e.g., hydraulic, semi-hydraulic, linear actuator(s), gas-assisted mechanisms and/or gearing systems.

As best illustrated in Fig. 11, housing halves 20a and 20b of housing 20, when assembled, form an internal cavity 52 which predefines the channel 54 within fixed handle 50 such that an entrance pathway 53 and an exit pathway 58 are formed for reciprocation of the t-shaped flange end 93 therein. Once assembled, two generally triangular-shaped members 57a and 57b are positioned in close abutment relative to one another to define a rail or track 59 therebetween. During movement of the flange 92 along the entrance and exit pathways 53 and 58, respectively, the t-shaped end 93 rides along track 59 between the two triangular members 57a and 57b according to the particular

dimensions of the triangularly-shaped members 57a and 57b, which, as can be appreciated, predetermines part of the overall pivoting motion of handle 40 relative to fixed handle 50.

Once actuated, handle 40 moves in a generally arcuate fashion towards fixed handle 50 about pivot 69 which causes link 65 to rotate proximally about pivots 67a and 67b which, in turn, cause cam-like link 36 to rotate about pivots 37 and 69 in a generally proximal direction. Movement of the cam-like link 36 imparts movement to the drive assembly 21 as explained in more detail below. Moreover, proximal rotation of the link 65 about pivots 67a and 67b also causes a distal end 63 of link 65 to release, i.e., "unlock", the trigger assembly 70 for selective actuation. This feature is explained in detail with reference to Figs. 21-29 and the operation of the knife assembly 200.

Turning now to Fig. 12 which shows an exploded view of the shaft 12 and end effector assembly 100. As mentioned above, shaft 12 includes distal and proximal ends 14 and 16, respectively. The distal end 14 is bifurcated and includes ends 14a and 14b which, together, define a cavity 18 for receiving the end effector assembly 100. The proximal end 16 includes a pair of notches 17a (Fig. 29) and 17b (Fig. 11) which are dimensioned to engage corresponding detents 83a and 83b (Fig. 13) of the rotating assembly 80. As can be appreciated, actuation of the rotation assembly 80 rotates the shaft 12 which, in turn, rotates the end effector assembly 100 to manipulate and grasp tissue 420.

Shaft 12 also includes a pair of longitudinally-oriented channels 19a (Fig. 15) and 19b (Fig. 12) which are each dimensioned to carry an electrosurgical cable lead 310a and 310b, respectively, therein for ultimate connection to each jaw member 120 and 110, respectively, as explained in more detail with reference to Figs. 14-17 below. Shaft 12 also includes a pair of longitudinally oriented slots 197a and 197b disposed on ends 14a and 14b, respectively. Slots 197a and 197b are preferable dimensioned to allow longitudinal reciprocation of a cam pin 170 therein which, as explained below with reference to Figs. 23 and 24, causes movement of the opposing jaw member 110 and 120 from the open to closed positions.

Shaft 12 also includes a pair of sockets 169a and 169b disposed at distal ends 14a and 14b which are dimensioned to receive a corresponding pivot pin

160. As explained below, pivot pin 160 secures jaws 110 and 120 to the shaft 12 between bifurcated distal ends 14a and 14b and mounts the jaw members 110 and 120 such that longitudinal reciprocation of the cam pin 170 rotates jaw members 110 and 120 about pivot pin 160 from the open to closed positions.

Shaft 12 is preferably dimensioned to slidingly receive a knife tube 34 therein which engages the knife assembly 200 such that longitudinal movement of the knife tube 34 actuates the knife assembly 200 to divide tissue 420 as explained below with respect to Figs. 29-31. Knife tube 34 includes a rim 35 located at a proximal end thereof and a pair of opposing notches 230a and 230b (Figs. 25 and 30) located at a distal end 229 thereof. As best shown in Fig. 13, rim 35 is dimensioned to engage a corresponding sleeve 78 disposed at a distal end of the trigger assembly 70 such that distal movement of the sleeve 78 translates the knife tube 34 which, in turn, actuates the knife assembly 200. A seal 193 may be mounted atop the knife tube 34 and positioned between the knife tube 34 and the shaft 12. It is envisioned that the seal 193 may be dimensioned to facilitate reciprocation of the knife tube 34 within the shaft 12 and/or to protect the other, more sensitive, internal operating components of the forceps from undesirable fluid inundation during surgery. Seal 193 may also be employed to control/regulate pneumo-peritoneal pressure leakage through forceps 10 during surgery. Seal 193 preferably includes a pair of opposing bushings 195a and 195b which assure consistent and accurate reciprocation of the knife tube 34 within shaft 12 (See Fig 15).

Notches 230a and 230b are preferably dimensioned to engage a corresponding key-like interface 211 of the knife assembly 200 which includes a pair of opposing detents 212a and 212b and a pair of opposing steps 214a and 214b. As best illustrated in Figs. 25 and 30, each detent and step arrangement, e.g., 212a and 214a, respectively, securely engages a corresponding notch, e.g., 230a, such that the distal end of the step 214a abuts the distal end 229 of the knife tube 34. It is envisioned that engaging the knife tube 34 to the knife assembly 200 in this manner will assure consistent and accurate distal translation of the knife tube 34 through the tissue 420.

As can be appreciated from the present disclosure, the knife tube 34 and knife assembly 200 are preferably assembled to operate independently from

the operation of the drive assembly 21. However and as described in more detail below, knife assembly 200 is dependent on the drive assembly 21 for activation purposes, i.e., the activation/movement of the drive assembly 21 (via handle assembly 30 and the internal working components thereof) "unlocks" the knife assembly 200 for selective, separation of the tissue. For the purposes herein, the drive assembly 21 consists of both the drive rod 32 and the compression mechanism 24 which includes a number of cooperative elements which are described below with reference to Fig. 13. It is envisioned that arranging the drive assembly 21 in this fashion will enable facile, selective engagement of the drive rod 32 within the compression mechanism 24 for assembly purposes.

Although the drawings depict a disposable version of the presently disclosed forceps 10, it is contemplated that the housing 20 may include a release mechanism (not shown) which enables selectively replacement of the drive rod 32 for disposal purposes. In this fashion, the forceps will be considered "partially disposable" or "reposable", i.e., the shaft 12, end effector assembly 100 and knife assembly 200 are disposable and/or replaceable whereas the housing 20 and handle assembly 30 are re-usable.

As best illustrated in Figs. 16 and 17, drive rod 32 includes a pair of chamfered or beveled edges 31a and 31b at a distal end thereof which are preferably dimensioned to allow facile reciprocation of the drive rod 32 through a knife carrier or guide 220 which forms a part of the knife assembly 200. A pin slot 39 is disposed at the distal tip of the drive rod 32 and is dimensioned to house the cam pin 170 such that longitudinal reciprocation of the drive rod 32 within the knife tube 34 translates the cam pin 170, which, in turn, rotates the jaw members 110 and 120 about pivot pin 160. As will be explained in more detail below with respect to Figs. 23 and 24, the cam pin 170 rides within slots 172 and 174 of the jaw members 110 and 120, respectively, which causes the jaw members 110 and 120 to rotate from the open to closed positions about the tissue 420.

The proximal end of the drive rod 32 includes a tab 33 which is preferably dimensioned to engage a corresponding compression sleeve 28 disposed within the compression mechanism 24. Proximal movement of the

sleeve 28 (as explained below with respect to Figs. 21-24) reciprocates (i.e., pulls) the drive rod 32 which, in turn, pivots the jaw members 110 and 120 from the open to closed positions. Drive rod 32 also includes a donut-like spacer or o-ring 95 which is dimensioned to maintain pneumo-peritoneal pressure during endoscopic procedures. It is also envisioned that o-ring 95 may also prevent the inundation of surgical fluids which may prove detrimental to the internal operating components of the forceps 10. O-ring 95 is made also be made from a material having a low coefficient of friction to facilitate uniform and accurate reciprocation of the drive rod 32 within the knife tube 34.

As mentioned above, the knife assembly 200 is disposed between opposing jaw members 110 and 120 of the end effector assembly 100. Preferably, the knife assembly 200 and the end effector assembly 100 are independently operable, i.e., the trigger assembly 70 actuates the knife assembly 200 and the handle assembly 30 actuates the end effector assembly 100. Knife assembly 200 includes a bifurcated knife bar or rod 210 having two forks 210a and 210b and a knife carrier or guide 220. Knife forks 210a and 210b include the above-described key-like interfaces 211 (composed of steps 214a, 214b and detents 212a, 212b, respectively) disposed at the proximal end thereof for engaging the knife tube 34 (as described above) and a common distal end 206 which carries a blade 205 thereon for severing tissue 420. Preferably, each fork 210a and 210b includes a taper 213a and 213b, respectively, which converge to form common distal end 206. It is envisioned that the tapers 213a and 213b facilitate reciprocation of the knife blade 205 through the end effector assembly 100 as described in more detail below and as best illustrated in Fig. 30.

Each fork 210a and 210b also includes a tapered shoulder portion 221a and 221b disposed along the outer periphery thereof which is dimensioned to engage a corresponding slot 223a and 223b, respectively, disposed in the knife carrier or guide 220 (See Fig. 16). It is envisioned that this shoulder portion 221a, 221b and slot 223a, 223b arrangement may be designed to restrict and/or regulate the overall distal movement of the blade 205 after activation. Each fork 210a and 210b also includes an arcuately-shaped notch 215a and 215b, respectively disposed along the inward edge thereof which is

dimensioned to facilitate insertion of a roller or bushing 216 disposed between the jaw members 110 and 120 during assembly.

As mentioned above, knife assembly 200 also includes a knife carrier or guide 220 which includes opposing spring tabs 222a and 222b at a proximal end thereof and upper and lower knife guides 224a and 224b, respectively, at the distal end thereof. The inner facing surface of each spring tab, e.g., 222b, is preferably dimensioned to matingly engage a corresponding chamfered edge, e.g., 31b of the drive rod 32 (Fig. 16) and the outer facing surface is preferably dimensioned for friction-fit engagement with the inner periphery of the shaft 12. As best seen in Fig. 12, knife carrier 220 also includes a drive rod channel 225 defined therethrough which is dimensioned to allow reciprocation of the drive rod 32 during the opening and closing of the jaw members 110 and 120. Knife guide 220 also includes rests 226a and 226b which extend laterally therefrom which abut the proximal ends 132, 134 of the jaw members 110 and 120 when disposed in the closed position.

Knife guides 224a and 224b preferably include slots 223a and 223b, respectively, located therein which guide the knife forks 210a and 210b therealong during activation to provide consistent and accurate reciprocation of the knife blade 205 through the tissue 420. It is envisioned that slots 223a and 223b also restrict undesirable lateral movements of the knife assembly 200 during activation. Preferably, the knife carrier 220 is positioned at a point slightly beyond the shoulder portions 221a and 221b when assembled.

The knife assembly 200 also includes a roller or bushing 216 which is dimensioned to mate with the inner peripheral edge of each fork 210a and 210b such that, during activation, the forks 210a and 210b glide over the roller or bushing 216 to assure facile and accurate reciprocation of the knife assembly 200 through the tissue 420. Bushing 216 is also dimensioned to seat between opposing jaw members 110 and 120 and is preferably secured therebetween by pivot pin 160. As mentioned above, the arcuately-shaped notches 215a and 215b facilitate insertion of the bushing 216 during assembly.

The end effector assembly 100 includes opposing jaw members 110 and 120 which are seated within cavity 18 defined between bifurcated ends 14a and 14b of shaft 12. Jaw members 110 and 120 are generally symmetrical and

include similar component features which cooperate to permit facile rotation about pivot pin 160 to effect the sealing and dividing of tissue 420. As a result and unless otherwise noted, only jaw member 110 and the operative features associated therewith are describe in detail herein but as can be appreciated, many of these features apply to jaw member 120 as well.

More particularly, jaw member 110 includes a pivot flange 166 which has an arcuately-shaped inner surface 167 which is dimensioned to allow rotation of jaw member 110 about bushing 216 and pivot pin 160 upon reciprocation of drive rod 32 as described above. Pivot flange 166 also includes a cam slot 172 which is dimensioned to engage cam pin 170 such that longitudinal movement of the drive rod 32 causes the cam pin 170 to ride along cam slot 172. It is envisioned that cam slot 172 may be dimensioned to allow different rotational paths depending upon a particular purpose or to achieve a particular result. For example, commonly assigned, co-pending U.S. Application Serial No. 09/177,950 which is hereby incorporated by reference in its entirety herein, describes a two-stage cam slot arrangement which, as can be appreciated, provides a unique rotational path for the jaw members about the pivot point.

Pivot flange 166 also includes a recess 165 which is preferably dimensioned to secure one free end of the bushing 216 between jaw members 110 and 120. The inner periphery of recess 165 is preferably dimensioned to receive pivot pin 160 therethrough to secure the jaw member 110 to the shaft 12. Jaw member 120 includes a similar recess 175 (Fig. 14) which secures the opposite end of bushing 216 and jaw member 120 to shaft 12.

Jaw member 110 also includes a jaw housing 116, an insulative substrate or insulator 114 and an electrically conducive surface 112. Jaw housing 116 includes a groove (not shown - See groove 179 of jaw member 120) defined therein which is dimensioned to engage a ridge-like interface 161 disposed along the outer periphery of insulator 114. Insulator 114 is preferably dimensioned to securely engage the electrically conductive sealing surface 112. This may be accomplished by stamping, by overmolding, by overmolding a stamped electrically conductive sealing plate and/or by overmolding a metal injection molded seal plate.

All of these manufacturing techniques produce an electrode having an electrically conductive surface 112 which is substantially surrounded by an insulating substrate 114. The insulator 114, electrically conductive sealing surface 112 and the outer, non-conductive jaw housing 116 are preferably dimensioned to limit and/or reduce many of the known undesirable effects related to tissue sealing, e.g., flashover, thermal spread and stray current dissipation. Alternatively, it is also envisioned that the jaw members 110 and 120 may be manufactured from a ceramic-like material and the electrically conductive surface(s) 112 are coated onto the ceramic-like jaw members 110 and 120.

Preferably, the electrically conductive sealing surface 112 may also include a pinch trim 119 (Fig. 25) which facilitates secure engagement of the electrically conductive surface 112 to the insulating substrate 114 and also simplifies the overall manufacturing process. It is envisioned that the electrically conductive sealing surface 112 may also include an outer peripheral edge which has a radius and the insulator 114 meets the electrically conductive sealing surface 112 along an adjoining edge which is generally tangential to the radius and/or meets along the radius. Preferably, at the interface, the electrically conductive surface 112 is raised relative to the insulator 114. These and other envisioned embodiments are discussed in concurrently-filed, co-pending, commonly assigned Application Serial No. PCT/US01/11412 entitled "ELECTROSURGICAL INSTRUMENT WHICH REDUCES COLLATERAL DAMAGE TO ADJACENT TISSUE" by Johnson et al. and concurrently-filed, co-pending, commonly assigned Application Serial No. PCT/US01/11411 entitled "ELECTROSURGICAL INSTRUMENT WHICH IS DESIGNED TO REDUCE THE INCIDENCE OF FLASHOVER" by Johnson et al.

Insulator 114 also includes an inwardly facing finger 162 which abuts pivot flange 166 and is designed to restrict / reduce proximal tissue spread and/or isolate the electrically conductive sealing surface 112 from the remaining end effector assembly 100 during activation. Preferably, the electrically conductive surface 112 and the insulator 114, when assembled, form a longitudinally-oriented channel 168a, 168b defined therethrough for

reciprocation of the knife blade 205. More particularly, and as best illustrated in Fig. 14, insulator 114 includes a first channel 168b which aligns with a second channel 168a on electrically conductive sealing surface 112 to form the complete knife channel. It is envisioned that the knife channel 168a, 168b facilitates longitudinal reciprocation of the knife blade 205 along a preferred cutting plane "B-B" to effectively and accurately separate the tissue 420 along the formed tissue seal 425 (See Figs. 27, 28 and 31.

As mentioned above, jaw member 120 include similar elements which include: a pivot flange 176 which has an arcuately-shaped inner surface 177, a cam slot 174, and a recess 175; a jaw housing 126 which includes a groove 179 which is dimensioned to engage a ridge-like interface 171 disposed along the outer periphery of an insulator 124; the insulator 124 which includes an inwardly facing finger 172 which abuts pivot flange 176; and an electrically conducive sealing surface 122 which is dimensioned to securely engage the insulator 124. Likewise, the electrically conductive surface 122 and the insulator 124, when assembled, form a longitudinally-oriented channel 178a, 178b defined therethrough for reciprocation of the knife blade 205.

Preferably, the jaw members 110 and 120 are electrically isolated from one another such that electrosurgical energy can be effectively transferred through the tissue 420 to form seal 425. For example and as best illustrated in Figs. 14 and 15, each jaw member, e.g., 110, includes a uniquely-designed electrosurgical cable path disposed therethrough which transmits electrosurgical energy to the electrically conductive sealing surfaces 112, 122. More particularly, jaw member 110 includes a cable guide 181a disposed atop pivot flange 166 which directs cable lead 310a towards an aperture 188 disposed through jaw housing 116. Aperture 188, in turn, directs cable lead 310a towards electrically conductive sealing surface 112 through a window 182 disposed within insulator 114. A second cable guide 181b secures cable lead 310a along the predefined cable path through window 182 and directs a terminal end 310a' of the cable lead 310a into crimp-like electrical connector 183 disposed on an opposite side of the electrically conductive sealing surface 112. Preferably, cable lead 310a is held loosely but securely along the cable path to permit rotation of the jaw member 110 about pivot 169.

As can be appreciated, this isolates electrically conductive sealing surface 112 from the remaining operative components of the end effector assembly 100 and shaft 12. Jaw member 120 includes a similar cable path disposed therein and therethrough which includes similarly dimensioned cable guides, apertures and electrical connectors which are not shown in the accompanying illustrations.

Figs. 15-17 also show the presently disclosed feed path for both electrosurgical cable leads 310a and 310b along the outer periphery of the shaft 12 and through each jaw member 110 and 120. More particularly, Fig. 15 shows a cross section of the electrosurgical cable leads 310a and 310b disposed within channels 19a and 19b, respectively, along shaft 12. Figs. 16 and 17 show the feed path of the cable leads 310a and 310b from the opposite channels 19a and 19b of the shaft 12 through the pivot flanges 166 and 176 of the jaw members 110 and 120, respectively. It is contemplated that this unique cable feed path for cable leads 310a and 310b from the shaft 12 to the jaw members 110 and 120 not only electrically isolates each jaw member 100 and 120 but also allows the jaw members 110 and 120 to pivot about pivot pin 160 without unduly straining or possibly tangling the cable leads 310a and 310b. Moreover, it is envisioned that the crimp-like electrical connector 183 (and the corresponding connector in jaw member 120) greatly facilitates the manufacturing and assembly process and assures a consistent and tight electrical connection for the transfer of energy through the tissue 420. As best shown in Fig. 17, the outer surface of shaft 12 may be covered by heat shrink tubing 500 or the like which protects the cable leads 310a and 310b from undue wear and tear and secures cable leads 310a and 310b within their respective channels 19a and 19b.

Figs. 18A and 18B show the feed path of the cable leads 310a and 310b through the rotating assembly 80 which, again, allows the user added flexibility during the use of the forceps 10 due to the uniqueness of the feed path. More particularly, Fig. 18A shows the feed path of cable lead 310a through half 80a of the rotating assembly 80 and Fig. 18B shows the path of cable leads 310a and 310b as the cable leads 310a and 310b feed through the instrument housing 20a, through half 80a of the rotating assembly 80 and to the channels

19a and 19b of the shaft 12. Fig. 18A only shows the feed path of cable lead 310a through half 80a of the rotating assembly 80, however, as can be appreciated, cable lead 310b (shown broken in Fig. 19) is positioned in a similar fashion within half 80b of rotating assembly 80.

As best illustrated in Fig. 18A, it is envisioned that cable leads 310a and 310b are fed through respective halves 80a and 80b of the rotating assembly 80 in such a manner to allow rotation of the shaft 12 (via rotation of the rotating assembly 80) in the clockwise or counter-clockwise direction without unduly tangling or twisting the cable leads 310a and 310b. More particularly, each cable lead, e.g., 310a, is looped through each half 80a of the rotating assembly 80 to form slack-loops 321a and 321b which traverse either side of longitudinal axis "A". Slack-loop 321a redirects cable lead 310a across one side of axis "A" and slack-loop 321b returns cable lead 310a across axis "A". It is envisioned that feeding the cable leads 310a and 310b through the rotating assembly 80 in this fashion allows the user to rotate the shaft 12 and the end effector assembly 100 without unduly straining or tangling the cable leads 310a and 310b which may prove detrimental to effective sealing. Preferably, this loop-like cable feed path allows the user to rotate the end effector assembly 100 about 180 degrees in either direction without straining the cable leads 310a and 310b. The presently disclosed cable lead feed path is envisioned to rotate the cable leads 310a and 310b approximately 178 degrees in either direction.

Fig. 19 shows an internal view of half 80a of the rotating assembly 80 as viewed along axis "A" to highlight the internal features thereof. More particularly, at least one stop 88 is preferably positioned within each rotating half 80a and 80b which operates to control the overall rotational movement of the rotating assembly 80 to about 180 degree in either direction. The stop member 88 is dimensioned to interface with a corresponding notch 309c disposed along the periphery of outer flange 309 to prevent unintended over-rotation of the rotating assembly 80 which may unduly strain one or both of the cable leads 310a and 310b.

Fig. 18B shows the feed path of the electrical cable leads 310a and 310b from the housing 20a, through the rotating assembly 80 and to the shaft 12. It is envisioned that the cable leads 310a and 310b are directed through each part

of the forceps 10 via a series of cable guide members 311a-311g disposed at various positions through the housing 20 and rotating assembly 80. As explained below, a series of mechanical interfaces, e.g., 309a, 309b (Fig. 13) and 323a, 323b (Fig. 13) may also be dimensioned to contribute in guiding cables 310a and 310b through the housing 20 and rotating assembly 80.

Turning back to Fig. 13 which shows the exploded view of the housing 20, rotating assembly 80, trigger assembly 70 and handle assembly 30, it is envisioned that all of these various component parts along with the shaft 12 and the end effector assembly 100 are assembled during the manufacturing process to form a partially and/or fully disposable forceps 10. For example and as mentioned above, the shaft 12 and/or end effector assembly 100 may be disposable and, therefore, selectively/releasably engagable with the housing 20 and rotating assembly 80 to form a partially disposable forceps 10 and/or the entire forceps 10 may be disposable after use.

Housing 20 is preferably formed from two housing halves 20a and 20b which engage one another via a series of mechanical interfaces 307a, 307b, 307c and 308a, 308b, 308c respectively, to form an internal cavity 300 for housing the hereindescribed internal working components of the forceps 10. For the purposes herein, housing halves 20a and 20 are generally symmetrical and, unless otherwise noted, a component described with respect to housing half 20a will have a similar component which forms a part of housing half 20b.

Housing half 20a includes proximal and distal ends 301a and 303a, respectively. Proximal end 301a is preferably dimensioned to receive an electrical sleeve 99 which secures the electrosurgical cable 310 (Fig. 1) within the housing 20. As best shown in Figs. 9 and 21, paired cable 310 splits into two electrosurgical cable leads 310a and 310b which are subsequently fed through the housing 20 to ultimately transmit different electrical potentials to the opposing jaw members 110 and 120. As mentioned above, various cable guides 311a-311g are positioned throughout the housing 20 and the rotating assembly 80 to direct the cable leads 310a and 310b to the channels 19a and 19b disposed along the outer periphery of the shaft 12.

The distal end 303a is generally arcuate in shape such that, when assembled, distal ends 303a and 303b form a collar 303 (Fig. 13) which

extends distally from the housing 20. Each distal end 303a, 303b of the collar 303 includes an outer flange 309a, 309b and a recess 323a, 323b which cooperate to engage corresponding mechanical shoulders 84a, 84b (Fig. 29) and flanges 87a, 87b, respectively, disposed within the rotating assembly 80. As can be appreciated, the interlocking engagement of the flanges 309a, 309b with the shoulders 84a, 84b and the recesses 323a, 323b with the flanges 87a, 87b are dimensioned to allow free rotation about of the rotating assembly 80 about collar 303 when assembled. As mentioned above, the stop member(s) 88 and the notch(es) mechanically cooperate to limit rotational movement of the rotating assembly 80 to avoid straining cable leads 310a and 310b.

Each distal end 303a, 303b of collar 303 also includes an inner cavity 317a and 317b (Figs. 9 and 21), respectively, defined therein which is dimensioned to permit free rotation of the shaft 12, knife tube 34 and cable leads 310a and 310b housed therein. A plurality of detents 89a located within rotating assembly 80 engage a corresponding plurality of sockets 89b (Fig. 13) disposed within rotating half 80b to poise the rotating assembly 80 in rotational relationship atop collar 303.

Housing half 20a also includes a plurality of hub-like pivot mounts 329a, 331a and 333a which as explained in more detail below with respect to the operation of the instrument, cooperate with opposite hub-like pivot mounts (shown in phantom in Fig. 13) disposed on housing half 20b to engage the free ends of pivot pins 37, 67b and 77, respectively, which are associated with the different operating components described below. Preferably, each of these mounts 329a, 331a and 333a provide a fixed point of rotation for each pivoting element, namely, cam link 36, handle link 65 and trigger assembly 70, respectively.

As best seen in Figs. 11 and 13, fixed handle 50 which takes shape upon the assembly of housing 20 includes a scallop-like outer surface 51 and an internal cavity 52 defined therein. As mentioned above with respect to the discussion of Fig. 11, these elements and the other internal elements of the fixed handle 50 cooperate with movable handle 40 to activates the four-bar mechanical linkage which, in turn, actuates the drive assembly 21 for imparting

movement of the opposing jaw members 110 and 120 relative to one another to grasp tissue 420 therebetween.

The handle assembly 30 which includes the above-mentioned fixed handle 50 and movable handle 40 also includes the cam link 36 which is generally triangular in shape. The cam link 36 includes an upper piston 38, a fixed pivot 37 and a handle pivot 69. Cam link 36 is assembled within the internal cavity 300 of housing 20 between housing halves 20a and 20b. More particularly, fixed pivot 37 is rotatingly mounted within fixed mounts 329a and 329b between opposing housing halves 20a and 20b and the handle pivot 69 is rotatingly mounted within the bifurcated end of handle 40 through apertures 68a and 68b. Cam piston 38 is poised within a longitudinal channel 25c defined through the drive assembly 70 (explained in further detail below with respect to the discussion of the drive assembly 70) in abutting relationship with a compression tab 25 such that movement of the handle 40 rotates piston 38 proximally against coil spring 22. These and the other details relating to the operational features are discussed below with reference to Figs. 21-29.

Link 65 is also associated with the handle assembly 30 and forms an integral part of the four-bar mechanical linkage. Link 65 includes a distal end 63 and two pivot pins 67a and 67b. Pivot pin 67a engages apertures 68a and 68b disposed within the movable handle 40 and pivot 67b engages fixed mounts 331a and 331b between housing halves 20a and 20b such that movement of the handle 40 towards fixed handle 50 pivots link 65 about pivots 67a and 67b. As explained in more detail below, distal end 63 acts as a lockout for the trigger assembly 70.

Movable handle 40 includes a flange 92 which is preferably mounted to the movable handle 40 by pins 46a and 46b which engage apertures 41a and 41b disposed within handle 40 and apertures 91a and 91b disposed within flange 92, respectively. Other methods of engagement are also contemplated, snap-lock, spring tab, etc. Flange 92 also includes a t-shaped distal end 93 which, as mentioned above with respect to Fig. 11, rides within a predefined channel 54 disposed within fixed handle 50. Additional features with respect to the t-shaped end 93 are explained below in the detailed discussion of the operational features of the forceps 10.

A drive assembly 21 is preferably positioned within the housing 20 between housing halves 20a and 20b. As discussed above, the drive assembly 21 includes the previously described drive rod 32 and the compression mechanism 24. Compression mechanism 24 includes a compression sleeve 27 which is telescopically and/or slidingly disposed within a spring mount 26. The distal end 28 of the compression sleeve 27 is preferably C-shaped and dimensioned to engage the tab 33 disposed at the proximal end of drive rod 32 such that longitudinal movement of the compression sleeve 27 actuates the drive rod 32. The proximal end of the compression sleeve 27 is dimensioned to engage a barbell-shaped compression tab 25 which is disposed within a longitudinal slot 25s of the spring mount 26. The compression sleeve 27 also includes a longitudinal slot or channel 25c which is longitudinally aligned with slot 25s and is dimensioned to receive the cam piston 38 of the cam link 36 described above.

The proximal end of spring mount 26 includes a circular flange 23 which is dimensioned to bias the compression spring 22 once the compression mechanism 24 is assembled and seated within housing 20 (Fig. 11). The distal end of spring mount 26 includes a flange 25f which restricts distal movement of the tab 25 to within the slot 25s of the spring mount 26 and biases the opposite end the spring 22.

As best seen in Fig. 11, once assembled, spring 22 is poised for compression atop spring mount 26 upon actuation of the handle assembly 30. More particularly, movement of the cam piston 38 within slot 25c (via movement of handle assembly 30) moves the tab 25 atop slot 25s and reciprocates the compression sleeve 27 within the spring mount 26 to compress the spring 22. Proximal movement of the compression sleeve 27 imparts proximal movement to the drive rod 32 which closes jaw members 110 and 120 about tissue 420 (Fig. 26). Compression of the spring 22 may be viewed through one or more windows 340 disposed within the housing halves, e.g., 20b.

Fig. 13 also shows the trigger assembly 70 which activates the knife assembly 200 as described above with respect to Fig. 12. More particularly, trigger assembly 70 includes an actuator 73 having a cuff-like distal end 78 which is dimensioned to receive the proximal rim 35 of the knife tube 34. A

drive pin 74 extends laterally from the proximal end of actuator 73. Trigger assembly 70 also includes an ergonomically enhanced finger tab 72 having opposing wing-like flanges 72a and 72b which are envisioned to facilitate gripping and firing of the trigger assembly during surgery.

As best shown in Fig. 11, the compression sleeve 27 is dimensioned to slide internally within actuator 73 when the forceps 10 is assembled. Likewise, the actuator 73, when activated, can slide distally along the outer periphery of compression sleeve 27 to actuate the knife assembly 200 as described above with respect to Fig. 12. The drive pin 74 is dimensioned to ride along a pair of guide rails 71a and 71b disposed within a bifurcated tail portion of finger tab 72 which includes ends 76a and 76b, respectively.

A hinge or pivot pin 77 mounts the finger tab 72 between housing halves 20a and 20 within mounts 333a and 333b. A torsion spring 75 may also be incorporated within the trigger assembly 70 to facilitate progressive and consistent longitudinal reciprocation of the actuator 73 and knife tube 34 to assure reliable separation along the tissue seal 425 (Figs. 27 and 28). In other words, the trigger assembly 70 is configured in a proximal, "pre-loaded" configuration prior to activation. This assures accurate and intentional reciprocation of the knife assembly 200. Moreover, it is envisioned that the "pre-load" configuration of the torsion spring 75 acts as an automatic recoil of the knife assembly 200 to permit repeated reciprocation through the tissue as needed. As mentioned above, a plurality of gripping elements 71 is preferably incorporated atop the finger tab 72 and wing flanges 72a and 72b to enhance gripping of the finger tab 72.

Preferably, the trigger assembly 70 is initially prevented from firing due to the unique configuration of the distal end 63 of the link 65 which abuts against the finger tab 72 and "locks" the trigger assembly 70 prior to actuation of the handle assembly 30. Moreover, it is envisioned that the opposing jaw members 110 and 120 may be rotated and partially opened and closed without unlocking the trigger assembly 70 which, as can be appreciated, allows the user to grip and manipulate the tissue 420 without premature activation of the knife assembly 200. As mentioned below, only when the t-shaped end 93 of flange 92 is completely reciprocated within channel 54 and seated within a pre-defined

catch basin 62 (explained below) will the distal end 63 of link 65 move into a position which will allow activation of the trigger assembly 70.

The operating features and relative movements of the internal working components of the forceps 10 are shown by phantom representation and directional arrows and are best illustrated in Figs. 21-29. As mentioned above, when the forceps 10 is assembled a predefined channel 54 is formed within the cavity 52 of fixed handle 50. The channel 54 includes entrance pathway 53 and an exit pathway 58 for reciprocation of the flange 92 and the t-shaped end 93 therein. Once assembled, the two generally triangular-shaped members 57a and 57b are positioned in close abutment relative to one another and define track 59 disposed therebetween.

More particularly, Figs. 21 and 22 show the initial actuation of handle 40 towards fixed handle 50 which causes the free end 93 of flange 92 to move generally proximally and upwardly along entrance pathway 53. During movement of the flange 92 along the entrance and exit pathways 53 and 58, respectively, the t-shaped end 93 rides along track 59 between the two triangular members 57a and 57b.

As the handle 40 is squeezed and flange 92 is incorporated into channel 54 of fixed handle 50, the cam link 36, through the mechanical advantage of the four-bar mechanical linkage, is rotated generally proximally about pivots 37 and 69 such that the cam piston 38 biases tab 25 which compresses spring 22 against flange 23 of the spring mount (Fig. 23). Simultaneously, the drive rod 32 is pulled proximally by the compression sleeve 27 which, in turn, causes cam pin 170 to move proximally within cam slots 172 and 174 and close the jaw members 110 and 120 relative to one another (Fig. 24). It is envisioned that channel 197 may be dimensioned slightly larger than needed to take into account any dimensional inconsistencies with respect to manufacturing tolerances of the various operating components of the end effector assembly 100 (Fig. 24)

It is envisioned that the utilization of a four-bar linkage will enable the user to selectively compress the coil spring 22 a specific distance which, in turn, imparts a specific load on the drive rod 32. The drive rod 32 load is converted to a torque about the jaw pivot 160 by way of cam pin 170. As a result, a

specific closure force can be transmitted to the opposing jaw members 110 and 120. It is also contemplated, that window 340 disposed in the housing 20 may include graduations, visual markings or other indicia which provide feedback to the user during compression of the handle assembly 30. As can be appreciated, the user can thus selectively regulate the progressive closure forces applied to the tissue 420 to accomplish a particular purpose or achieve a particular result. For example, it is envisioned that the user may progressively open and close the jaw members 110 and 120 about the tissue without locking the flange 93 in the catch basin 62. The window 340 may include a specific visual indicator which relates to the proximal-most position of flange 93 prior to engagement within the catch basin 62.

As mentioned above, the jaw members 110 and 120 may be opened, closed and rotated to manipulate tissue 420 until sealing is desired without unlocking the trigger assembly 70. This enables the user to position and re-position the forceps 10 prior to activation and sealing. More particularly, as illustrated in Fig. 4, the end effector assembly 100 is rotatable about longitudinal axis "A" through rotation of the rotating assembly 80. As mentioned above, it is envisioned that the unique feed path of the cable leads 310a and 310b through the rotating assembly 80, along shaft 12 and, ultimately, through the jaw members 110 and 120 enable the user to rotate the end effector assembly 100 about 180 degrees in both the clockwise and counterclockwise direction without tangling or causing undue strain on the cable leads 310a and 310b. As can be appreciated, this facilitates the grasping and manipulation of tissue 420.

A series of stop members 150a-150f are preferably employed on the inner facing surfaces of the electrically conductive sealing surfaces 112 and 122 to facilitate gripping and manipulation of tissue and to define a gap "G" (Fig. 24) between opposing jaw members 110 and 120 during sealing and cutting of tissue. A detailed discussion of these and other envisioned stop members 150a-150f as well as various manufacturing and assembling processes for attaching and/or affixing the stop members 150a-150f to the electrically conductive sealing surfaces 112, 122 are described in commonly-assigned, co-pending U.S. Application Serial No. PCT/US01/11413 entitled "VESSEL

SEALER AND DIVIDER WITH NON-CONDUCTIVE STOP MEMBERS" by Dycus et al. which is hereby incorporated by reference in its entirety herein.

Once the desired position for the sealing site 425 is determined and the jaw members 110 and 120 are properly positioned, handle 40 may be compressed fully such that the t-shaped end 93 of flange 92 clears a predefined rail edge 61 located atop the triangular-shaped members 57a and 57b. Once end 93 clears edge 61, distal movement of the handle 40 and flange 92, i.e., release, is redirected by edge 61 into a catch basin 62 located within the exit pathway 58. More particularly, upon a slight reduction in the closing pressure of handle 40 against handle 50, the handle 40 returns slightly distally towards entrance pathway 53 but is re-directed towards exit pathway 58. At this point, the release or return pressure between the handles 40 and 50 which is attributable and directly proportional to the release pressure associated with the compression of the drive assembly 70 causes the end 93 of flange 92 to settle or lock within catch basin 62. Handle 40 is now secured in position within fixed handle 50 which, in turn, locks the jaw members 110 and 120 in a closed position against the tissue 420.

At this point the jaws members 100 and 120 are fully compressed about the tissue 420 (Fig. 26). Moreover, the forceps 10 is now ready for selective application of electrosurgical energy and subsequent separation of the tissue 420, i.e., as t-shaped end 93 seats within catch basin 62, link 65 moves into a position to permit activation of the trigger assembly 70 (Figs. 21 and 29).

As the t-shaped end 93 of flange 92 becomes seated within catch basin 62, a proportional axial force on the drive rod 32 is maintained which, in turn, maintains a compressive force between opposing jaw members 110 and 120 against the tissue 420. It is envisioned that the end effector assembly 100 and/or the jaw members 110 and 120 may be dimensioned to off-load some of the excessive clamping forces to prevent mechanical failure of certain internal operating elements of the end effector 100.

As can be appreciated, the combination of the four-bar mechanical advantage along with the compressive force associated with the compression spring 22 facilitate and assure consistent, uniform and accurate closure pressure about the tissue 420.

By controlling the intensity, frequency and duration of the electrosurgical energy applied to the tissue 420, the user can either cauterize, coagulate/desiccate, seal and/or simply reduce or slow bleeding. As mentioned above, two mechanical factors play an important role in determining the resulting thickness of the sealed tissue and effectiveness of the seal 425, i.e., the pressure applied between opposing jaw members 110 and 120 and the gap distance "G" between the opposing sealing surfaces 112, 122 of the jaw members 110 and 120 during the sealing process. However, thickness of the resulting tissue seal 425 cannot be adequately controlled by force alone. In other words, too much force and the two jaw members 110 and 120 would touch and possibly short resulting in little energy traveling through the tissue 420 thus resulting in a bad tissue seal 425. Too little force and the seal 425 would be too thick.

Applying the correct force is also important for other reasons: to oppose the walls of the vessel; to reduce the tissue impedance to a low enough value that allows enough current through the tissue 420; and to overcome the forces of expansion during tissue heating in addition to contributing towards creating the required end tissue thickness which is an indication of a good seal 425.

Preferably, the electrically conductive sealing surfaces 112, 122 of the jaw members 110, 120, respectively, are relatively flat to avoid current concentrations at sharp edges and to avoid arcing between high points. In addition and due to the reaction force of the tissue 420 when engaged, jaw members 110 and 120 are preferably manufactured to resist bending. For example, the jaw members 110 and 120 may be tapered along the width thereof which is advantageous for two reasons: 1) the taper will apply constant pressure for a constant tissue thickness at parallel; 2) the thicker proximal portion of the jaw members 110 and 120 will resist bending due to the reaction force of the tissue 420.

It is also envisioned that the jaw members 110 and 120 may be curved in order to reach specific anatomical structures. For example, it is contemplated that dimensioning the jaw members 110 and 120 at an angle of about 50 degrees to about 70 degrees is preferred for accessing and sealing specific anatomical structures relevant to prostatectomies and cystectomies, e.g., the

dorsal vein complex and the lateral pedicles. It is also envisioned that the knife assembly 200 (or one or more of the components thereof) may be made from a semi-compliant material or may be multi-segmented to assure consistent, facile and accurate cutting through the above envisioned curved jaw member 110 and 120.

As mentioned above, at least one jaw member, e.g., 110 may include a stop member, e.g., 150a, which limits the movement of the two opposing jaw members 110 and 120 relative to one another (Figs. 6 and 7). Preferably, the stop member, e.g., 150a, extends from the sealing surface 112, 122 a predetermined distance according to the specific material properties (e.g., compressive strength, thermal expansion, etc.) to yield a consistent and accurate gap distance "G" during sealing (Fig. 24). Preferably, the gap distance between opposing sealing surfaces 112 and 122 during sealing ranges from about 0.001 inches to about 0.005 inches and, more preferably, between about 0.002 and about 0.003 inches.

Preferably, stop members 150a-150f are made from an insulative material, e.g., parylene, nylon and/or ceramic and are dimensioned to limit opposing movement of the jaw members 110 and 120 to within the above mentioned gap range. It is envisioned that the stop members 150a-150f may be disposed one or both of the jaw members 110 and 120 depending upon a particular purpose or to achieve a particular result. Many different configurations for the stop members 150a-150f are discussed in detail in commonly-assigned, co-pending U.S. Application Serial No. PCT/US01/11413 entitled "VESSEL SEALER AND DIVIDER WITH NON-CONDUCTIVE STOP MEMBERS" by Dycus et al. which is hereby incorporated by reference in its entirety herein.

One particular stop member configuration is shown in Fig. 33 which shows a single, circular stop member 150d disposed on either side of the knife channel 178a near the proximal-most portion of one of the sealing surfaces, e.g., 112. Two sets of circular stop member pairs 150e are disposed in the middle portion of sealing surface 112 on either side of the knife channel 178a and a single, circular stop member 150f is disposed at the distal-most portion of sealing surface 112 on either side of the knife channel 178a. It is envisioned

any of the various stop member configurations contemplated herein may be disposed on one or both sealing surfaces 112, 122 depending upon a particular purpose or to achieve a particular result. Moreover, it is envisioned that the stop members 150a-150f may be disposed on one side of the knife channel 178a according to a specific purpose.

Preferably, the non-conductive stop members 150a-150f are molded onto the jaw members 110 and 120 (e.g., overmolding, injection molding, etc.), stamped onto the jaw members 110 and 120 or deposited (e.g., deposition) onto the jaw members 110 and 120. For example, one technique involves thermally spraying a ceramic material onto the surface of the jaw member 110 and 120 to form the stop members 150a-150f. Several thermal spraying techniques are contemplated which involve depositing a broad range of heat resistant and insulative materials on various surfaces to create stop members for controlling the gap distance between electrically conductive surfaces 112, 122. Other techniques for disposing the stop members 150a-150f on the electrically conductive surfaces 112 and 122 are also contemplated, e.g., slide-on, snap-on, adhesives, molds, etc.

Further, although it is preferable that the stop members 150a-150f protrude about 0.001 inches to about 0.005 inches and preferably about 0.002 inches to about 0.003 inches from the inner-facing surfaces 112, 122 of the jaw member 110 and 120, in some cases it may be preferable to have the stop members 150a-150f protrude more or less depending upon a particular purpose. For example, it is contemplated that the type of material used for the stop members 150a-150f and that material's ability to absorb the large compressive closure forces between jaw members 110 and 120 will vary and, therefore, the overall dimensions of the stop members 150a-150f may vary as well to produce the desired gap distance "G".

In other words, the compressive strength of the material along with the desired or ultimate gap distance "G" required (desirable) for effective sealing are parameters which are carefully considered when forming the stop members 150a-150f and one material may have to be dimensioned differently from another material to achieve the same gap distance or desired result. For example, the compressive strength of nylon is different from ceramic and,

therefore, the nylon material may have to be dimensioned differently, e.g., thicker, to counteract the closing force of the opposing jaw members 110 and 120 and to achieve the same desired gap distance "G'" when utilizing a ceramic stop member.

As best shown in Figs. 27 and 28, as energy is being selectively transferred to the end effector assembly 100, across the jaw members 110 and 120 and through the tissue 420, a tissue seal 425 forms isolating two tissue halves 420a and 420b. At this point and with other known vessel sealing instruments, the user must remove and replace the forceps 10 with a cutting instrument (not shown) to divide the tissue halves 420a and 420b along the tissue seal 425. As can be appreciated, this is both time consuming and tedious and may result in inaccurate tissue division across the tissue seal 425 due to misalignment or misplacement of the cutting instrument along the ideal tissue cutting plane "B-B".

As explained in detail above, the present disclosure incorporates a knife assembly 200 which, when activated via the trigger assembly 70, progressively and selectively divides the tissue 420 along the ideal tissue plane "B-B" in an accurate and precise manner to effectively and reliably divide the tissue 420 into two sealed halves 420a and 420b (Fig. 31) with a tissue gap 430 therebetween. The reciprocating knife assembly 200 allows the user to quickly separate the tissue 420 immediately after sealing without substituting a cutting instrument through a cannula or trocar port 410. As can be appreciated, accurate sealing and dividing of tissue 420 is accomplished with the same forceps. It is envisioned that knife blade 205 may also be coupled to the same or an alternative electrosurgical energy source to facilitate separation of the tissue 420 along the tissue seal 425 (Not shown).

Moreover, it is envisioned that the angle of the blade tip 207 of the knife blade 205 may be dimensioned to provide more or less aggressive cutting angles depending upon a particular purpose. For example, the blade tip 207 may be positioned at an angle which reduces "tissue wisps" associated with cutting. More over, the blade tip 207 may be designed having different blade geometries such as serrated, notched, perforated, hollow, concave, convex etc. depending upon a particular purpose or to achieve a particular result.

Although it is envisioned that the blade tip 207 have a relatively sharp leading edge, it is also envisioned that the blade tip 207 may be substantially blunt or dull. More particularly, it is contemplated that the combination of the closure force between the jaw members 110 and 120 together with the uniquely designed stop members 150a-150f grip and hold the tissue firmly between the jaw members 110 and 120 to permit cutting of the tissue by blade tip 207 even if tip 207 is substantially blunt. As can be appreciated, designing the blade tip 207 blunt eliminates concerns relating to utilizing sharp objects with the surgical field.

Once the tissue 420 is divided into tissue halves 420a and 420b, the jaw members 110 and 120 may be opened by re-grasping the handle 40 as explained below. It is envisioned that the knife assembly 200 generally cuts in a progressive, uni-directional fashion (i.e., distally), however, it is contemplated that the knife blade may dimensioned to cut bi-directionally as well depending upon a particular purpose. For example, the force associated with the recoil of the trigger spring 75 may be utilized to with a second blade (not shown) which is designed to cut stray tissue wisps or dangling tissue upon recoil of the knife assembly.

As best shown in Fig. 32, re-initiation or re-grasping of the handle 40 again moves t-shaped end 93 of flange 92 generally proximally along exit pathway 58 until end 93 clears a lip 61 disposed atop triangular-shaped members 57a, 57b along exit pathway 58. Once lip 61 is sufficiently cleared, handle 40 and flange 92 are fully and freely releasable from handle 50 along exit pathway 58 upon the reduction of grasping/gripping pressure which, in turn, returns the jaw members 110 and 120 to the open, pre-activated position.

From the foregoing and with reference to the various figure drawings, those skilled in the art will appreciate that certain modifications can also be made to the present disclosure without departing from the scope of the present disclosure. For example, it may be preferable to add other features to the forceps 10, e.g., an articulating assembly to axially displace the end effector assembly 100 relative to the elongated shaft 12.

It is also contemplated that the forceps 10 (and/or the electrosurgical generator used in connection with the forceps 10) may include a sensor or

feedback mechanism (not shown) which automatically selects the appropriate amount of electrosurgical energy to effectively seal the particularly-sized tissue grasped between the jaw members 110 and 120. The sensor or feedback mechanism may also measure the impedance across the tissue during sealing and provide an indicator (visual and/or audible) that an effective seal has been created between the jaw members 110 and 120.

Moreover, it is contemplated that the trigger assembly 70 may include other types of recoil mechanism which are designed to accomplish the same purpose, e.g., gas-actuated recoil, electrically-actuated recoil (i.e., solenoid), etc. It is also envisioned that the forceps 10 may be used to dive / cut tissue without sealing. Alternatively, the knife assembly may be coupled to the same or alternate electrosurgical energy source to facilitate cutting of the tissue.

Although the figures depict the forceps 10 manipulating an isolated vessel 420, it is contemplated that the forceps 10 may be used with non-isolated vessels as well. Other cutting mechanisms are also contemplated to cut tissue 420 along the ideal tissue plane "B-B". For example, it is contemplated that one of the jaw members may include a cam-actuated blade member which is seated within one of the jaw members which, upon reciprocation of a cam member, is biased to cut tissue along a plane substantially perpendicular to the longitudinal axis "A".

Alternatively, a shape memory alloy (SMAs) may be employed to cut the tissue upon transformation from an austenitic state to a martenistic state with a change in temperature or stress. More particularly, SMAs are a family of alloys having anthropomorphic qualities of memory and trainability and are particularly well suited for use with medical instruments. SMAs have been applied to such items as actuators for control systems, steerable catheters and clamps. One of the most common SMAs is Nitinol which can retain shape memories for two different physical configurations and changes shape as a function of temperature. Recently, other SMAs have been developed based on copper, zinc and aluminum and have similar shape memory retaining features.

SMAs undergo a crystalline phase transition upon applied temperature and/or stress variations. A particularly useful attribute of SMAs is that after it is deformed by temperature/stress, it can completely recover its original shape on

being returned to the original temperature. This transformation is referred to as a thermoelastic martenistic transformation.

Under normal conditions, the thermoelastic martenistic transformation occurs over a temperature range which varies with the composition of the alloy, itself, and the type of thermal-mechanical processing by which it was manufactured. In other words, the temperature at which a shape is "memorized" by an SMA is a function of the temperature at which the martensite and austenite crystals form in that particular alloy. For example, Nitinol alloys can be fabricated so that the shape memory effect will occur over a wide range of temperatures, e.g., -270^0 to $+100^0$ Celsius.

Although the jaw members as shown and described herein depict the jaw members movable in a pivotable manner relative to one another to grasp tissue therebetween, it is envisioned that the forceps may be designed such that the jaw members are mounted in any manner which move one or both jaw members from a first juxtaposed position relative to one another to second contact position against the tissue.

It is envisioned that the outer surface of the end effectors may include a nickel-based material, coating, stamping, metal injection molding which is designed to reduce adhesion between the end effectors (or components thereof) with the surrounding tissue during activation and sealing. Moreover, it is also contemplated that the tissue contacting surfaces 112 and 122 of the end effectors may be manufactured from one (or a combination of one or more) of the following materials: nickel-chrome, chromium nitride, MedCoat 2000 manufactured by The Electrolizing Corporation of OHIO, inconel 600 and tin-nickel. The tissue contacting surfaces may also be coated with one or more of the above materials to achieve the same result, i.e., a "non-stick surface". Preferably, the non-stick materials are of a class of materials that provide a smooth surface to prevent mechanical tooth adhesions. As can be appreciated, reducing the amount that the tissue "sticks" during sealing improves the overall efficacy of the instrument.

Experimental results suggest that the magnitude of pressure exerted on the tissue by the seal surfaces 112 and 122 is important in assuring a proper surgical outcome. Tissue pressures within a working range of about 3 kg/cm^2 to

about 16 kg/cm^2 and, preferably, within a working range of 7 kg/cm^2 to 13 kg/cm^2 have been shown to be effective for sealing arteries and vascular bundles. Preferably, the four-bar handle assembly 30, spring 22 and drive assembly are manufactured and dimensioned such that the cooperation of these working elements, i.e., the four-bar handle assembly 30 (and the internal working components thereof), the spring 22 and drive assembly 21, maintain tissue pressures within the above working ranges. Alternatively, the handle assembly 30, the spring 22 or the drive assembly 30 may be manufactured and dimensioned to produce tissue pressures within the above working range independently of the dimensions and characteristic of the other of these working elements.

As mentioned above, it is also contemplated that the tissue sealing surfaces 112 and 122 of the jaw members 110 and 120 can be made from or coated with these non-stick materials. When utilized on the sealing surfaces 112 and 122, these materials provide an optimal surface energy for eliminating sticking due in part to surface texture and susceptibility to surface breakdown due electrical effects and corrosion in the presence of biologic tissues. It is envisioned that these materials exhibit superior non-stick qualities over stainless steel and should be utilized on the forceps 10 in areas where the exposure to pressure and electrosurgical energy can create localized "hot spots" more susceptible to tissue adhesion. As can be appreciated, reducing the amount that the tissue "sticks" during sealing improves the overall efficacy of the instrument.

As mentioned above, the non-stick materials may be manufactured from one (or a combination of one or more) of the following "non-stick" materials: nickel-chrome, chromium nitride, MedCoat 2000, Inconel 600 and tin-nickel. For example, high nickel chrome alloys, Ni200, Ni201 (~100% Ni) may be made into electrodes or sealing surfaces by metal injection molding, stamping, machining or any like process. Also and as mentioned above, the tissue sealing surfaces 112 and 122 may also be "coated" with one or more of the above materials to achieve the same result, i.e., a "non-stick surface". For example, Nitride coatings (or one or more of the other above-identified

materials) may be deposited as a coating on another base material (metal or nonmetal) using a vapor deposition manufacturing technique.

One particular class of materials disclosed herein has demonstrated superior non-stick properties and, in some instances, superior seal quality. For example, nitride coatings which include, but not are not limited to: TiN, ZrN, TiAlN, and CrN are preferred materials used for non-stick purposes. CrN has been found to be particularly useful for non-stick purposes due to its overall surface properties and optimal performance. Other classes of materials have also been found to reducing overall sticking. For example, high nickel/chrome alloys with a Ni/Cr ratio of approximately 5:1 have been found to significantly reduce sticking in bipolar instrumentation. One particularly useful non-stick material in this class is Inconel 600. Bipolar instrumentation having sealing surfaces 112 and 122 made from or coated with Ni200, Ni201 (~100% Ni) also showed improved non-stick performance over typical bipolar stainless steel electrodes.

By way of example, chromium nitride may be applied using a physical vapor deposition (PVD) process that applies a thin uniform coating to the entire electrode surface. This coating produces several effects: 1) the coating fills in the microstructures on the metal surface that contribute to mechanical adhesion of tissue to electrodes; 2) the coating is very hard and is a non-reactive material which minimizes oxidation and corrosion; and 3) the coating tends to be more resistive than the base material causing electrode surface heating which further enhances desiccation and seal quality.

The Inconel 600 coating is a so-called "super alloy" which is manufactured by Special Metals, Inc. located in Conroe Texas. The alloy is primarily used in environments which require resistance to corrosion and heat. The high Nickel content of Inconel makes the material especially resistant to organic corrosion. As can be appreciated, these properties are desirable for bipolar electrosurgical instruments which are naturally exposed to high temperatures, high RF energy and organic matter. Moreover, the resistivity of Inconel is typically higher than the base electrode material which further enhances desiccation and seal quality.

As disclosed herein the present invention relates to the transfer of electrosurgical energy though opposing electrically conductive sealing surfaces having different electrical potentials to effect vessel sealing. However, it is also contemplated that the presently disclosed embodiments discussed herein may be designed to seal the tissue structure using so-called "resistive heating" whereby the surfaces 112 and 122 are not necessarily electrically conductive surfaces. Rather, each of the surfaces 112 and 122 is heated much like a conventional "hot plate" such that the surfaces 112 and 122 cooperate to seal the tissue upon contact (or upon activation of a switch (not shown) which selectively heats each surface 112 and 122 upon activation). With this embodiment, the resistive heating is achieved using large heating blocks 1500 (See Fig. 35A and 35B), resistive heating wire, flexible foil heaters, resistance wire flexible heaters, and/or an externally heated element. By controlling the temperature between a range of about 125 to about 150 degrees Celsius, controlling the pressure between a range of about 100 psi to about 200 psi, and regulating the and gap distance.

It is also envisioned that the tissue may be sealed and/or fused using radio frequency (RF) energy. With this embodiment, the electrodes which transmit the RF energy may be configured as a large solid blocks or a multiple smaller blocks separated by an insulator. More particularly, the surgeon can selectively regulate the transmission of RF energy to a pair of thermally isolated jaw members 110 and 120 which, in turn, transmits the RF energy through the tissue which acts as a resistive medium. By regulating the RF energy, the temperature of the tissue is easily controlled. Moreover and as explained in the various embodiments described above, the closing pressure between the jaw members 110 and 120 may be selectively regulated as well by adjusting one or more of the elements of the handle assembly 30, e.g., movable handle 40, fixed handle 50, flange 92, track 54, etc.

Preferably, the closing pressure is in the range of about 100 to about 200psi. It has been determined that by controlling the RF energy and pressure and maintaining a gap distance "G" in the range of about 0.005 millimeters to about 0.015 millimeters between the conductive surfaces 112 and 122, effective and consistent tissue sealing may be achieved in a broad range of tissue types.

Alternatively, the forceps 10 may employ any combination of one or more of the above heating technologies and a switch (not shown) which allows the surgeon the option of the different heating technology.

Although the presently described forceps is designed to seal and divide tissue through standard-sized cannulas, one envisioned embodiment of the present disclosure includes a reduced-diameter shaft 12 and end effector assembly 100 which is specifically dimensioned to fit through a 5mm cannula. As can be appreciated, utilizing a smaller-sized surgical instrument can be extremely beneficial to the patient (i.e., reduced trauma, healing and scar tissue).

Preferably, the presently disclosed forceps is designed to electrically couple to a foot switch (not shown) which allows the surgeon to selectively control the electrosurgical energy transferred to the tissue. Figs. 34A and 34B show an alternate embodiment of the present disclosure wherein the forceps is activates via a handswitch 1200 located on the trigger assembly 70. More particularly, handswitch 1200 includes a pair of wafer switches 1210 which are disposed on either side of the trigger 70. The wafer switches 1210 cooperate with an electrical connector 1220 disposed within the housing 20. It is envisioned that the wafer switches 1210 are mounted relative to pivot pin 77 such that upon activation of the trigger assembly 70 the wafer switches 1210 are intentionally moved out of electrical contact with connector 1220. As can be appreciated, this prevents accidental activation of the jaw members 110 and 120 during cutting. Alternatively, other safety measures may also be employed, e.g., a cover plate which insulates the switches 1210 from the connector 1220 upon actuation of the trigger assembly 70, a cut-off switch, etc.

As mentioned above, it is also envisioned that the knife blade 205 may be energized. It is envisioned that the wafer switches could be reconfigured such that in one position, the wafer switches activate the jaw members 110 and 120 upon actuation and in another position, the wafer switches activate the knife blade 205. Alternatively, the wafer switches may be designed as mentioned upon (i.e., with a single electrical connector 1220) which energizes both the blade 205 and the jaw members 110 and 120 simultaneously. In this case, the blade 205 may need to be insulated to prevent shorting.

As can be appreciated, locating the handswitch 1200 on the forceps 10 has many advantages. For example, the handswitch reduces the amount of electrical cable in the operating room and eliminates the possibility of activating the wrong instrument during a surgical procedure due to "line-of-sight" activation. Moreover, decommissioning the handswitch 1200 when the trigger is actuated eliminates unintentionally activating the device during the cutting process.

It is also envisioned that the handswitch 1200 may be disposed on another part of the forceps 10, e.g., the handle assembly 30, rotating assembly, housing 20, etc. In addition, although wafer switches are shown in the drawings, other types of switches employed which allow the surgeon to selectively control the amount of electrosurgical energy to the jaw members or the blade 205, e.g., toggle switches, rocker switches, flip switches, etc.

It is also contemplated that in lieu of a knife blade 205, the present disclosure may include a so-called "hot-wire" (not shown) interdisposed between the two jaw members 110 and 120 which is selectively activatable by the user to divide the tissue after sealing. More particularly, a separate wire is mounted between the jaw members, e.g., 110 and 120, and is selectively movable and energizable upon activation of the trigger assembly 70, a handswitch 1200, etc. It is also envisioned that the "hot wire" may be configured such that the user can move the wire in an inactivated or activated state which as can be appreciated would allow the user to cut the tissue on a reverse stroke if desired. For example, the hot wire may be secured to one jaw member, e.g., 110, and held in friction fit engagement against the other jaw member, e.g., 120, to allow the tissue or vessel to pass between the jaw members 110, 120 when grasping and/or when moving the hot wire in an inactivated state distally. Once sealed, the user retracts the wire while energizing the hot wire to cut the tissue on the revises stroke.

It is also contemplated that the hot wire may be segmented with each end secured to a respective jaw member 110, 120. This would allow the two opposing hot wires to freely pivot in one direction (i.e., to allow through movement of the tissue between the jaw members 110, 120 in one direction,

e.g., upon retraction) and limit the through movement of the tissue in the opposite direction.

In another embodiment, the hot wire may include a hot (i.e., uninsulated) leading edge and an insulated trailing edge which will prevent charring on the return stroke.

It is envisioned that the presently disclosed jaw members 110 and 120 can include intermittent sealing patterns 1460a (See Fig. 35C) and 1460b (See Fig. 35D). It is contemplated that the intermittent sealing patterns 1460a, 1460b promote healing by maintaining tissue viability and reducing collateral damage to tissue outside the tissue sealing area. It is know that reduced tissue damage promotes healing by reducing the chance of tissue necrosis through continued vascularization. The intermittent sealing patterns 1460a, 1460b of Fig. 35A and 35B, respectively, deliver thermal energy to controlled regions, isolated by insulation from neighboring seal regions. The patterns are preferably designed to maximize seal strength yet provide a feasible path for vascularization.

Figs. 36-38B show an alternate embodiment of the present disclosure wherein the forceps 10 includes a longitudinally reciprocating tube-like cutter 2000 disposed about the outer periphery of shaft 12. The cutter 2000 is preferably designed to cut tissue 420 along the above-identified ideal seal plane "B-B" after the tissue 420 is sealed which, as can be appreciated, typically requires the surgeon to re-grasp the tissue 420 to align the tube cutter 2000 to longitudinally reciprocate along the intended cutting path of seal plane "B-B". More particularly, the tube cutter 2000 includes an elongate tube 2012 having an interior chamber 2032 which slidingly reciprocates shaft 12 and a cutting portion 2014 having a generally U-shaped notched blade 2020. Preferably, the tube cutter 2000 is generally thin-walled having a thickness of approximately 1.0 - 5.0 mm.

A recessed or offset cutting area 2018 is provided adjacent the U-shaped blade 2020 and includes a pair of adjacent cutting edges 2022a and 2022b for cutting tissue 420 clamped by jaws members 110 and 120. As can be appreciated, the adjacent cutting edges 2022a and 2022b are disposed along the inner periphery of the U-shaped blade 2020.

Preferably, the recessed cutting area 2018, i.e., the U-shaped blade 2020, includes a chamfered or beveled surface 2024 which bevels inwardly from the outer surface of tube 2012 to avoid incidental contact with surrounding tissue during manipulation and handling, i.e., the inwardly-angled beveled surface 2024 avoids undesirable blade 2020 to tissue contact before intentional activation by the surgeon. Further, since intended cutting area 2018 is recessed, forceps 10 can still be used for positioning vessels or tissue 420 being held between jaw members 110 and 120 without the fear of cutting or nicking the tissue or vessels 420 during use. In one embodiment, the beveled surface 2024 is beveled at approximately a 30-45 degree angle from the outer surface of elongate tube 2012.

The cutting area 2014 also includes two arms 2025a and 2025b which extend distally from blade 2020. Preferably, the two arms 2025a and 2025b lie in substantially the same plane as the outer periphery of the elongated tube 2012 and are dimensioned to facilitate introduction or "feeding" of the tissue 420 into the recessed or offset cutting area 2018. More particularly, each arm 2025a and 2025b includes a straight portion 2030a and 2030b, respectively, which both cooperate to introduce tissue 420 into the cutting are 2018 upon distal movement of the tube cutter 2000 towards the tissue 420. A rounded distal end 2033a and 2033b may be included on one or both of the distal ends of the straight portions 2030a and 2030b, respectively, to facilitate delicate positioning the tissue 420 within the cutting area 2018. For example and as best shown in Fig. 36, the tissue 420 is initially introduced into the cutting area 2018 between distal ends 2033a and 2033b. As the cutter 2000 moves distally, i.e., upon activation as explained in more detail below, the tissue 420 is guided by the straight portions 2030a and 2030b into the cutting area 2018 and into contact with the cutting edges 2022a and 2022b.

Preferably, the cutter 2000 includes a mechanical actuator 2050 which activates the cutting 2000 once the tissue 420 is grasped and/or grasped and sealed between the jaw members 110 and 120. It is envisioned that the mechanical actuator 2050 can be manually (e.g., trigger) or automatically activated depending upon a particular purpose or upon activation of a particular event or timed sequence. The mechanical actuator 2050 may include one or

more safety features, e.g., lockout tabs, electrical circuits, sensor feedback mechanisms (not shown) to prevent accidental activation of the cutter 2000 during grasping or sealing. Simply, the cutter 2000 may be prevented from activation if the jaw members 110 and 120 are disposed in an open configuration. It is also envisioned that the cutter 2000 may be activated prior to or after vessel sealing depending upon a particular purpose. Moreover, and as best illustrated by Fig. 38B, the cutter 2000 may be coupled to a source of electrosurgical energy, e.g., RF, ultrasonic, etc., or resistively heated to facilitate cutting. For example, a second electrosurgical generator 2060 (or the same generator which energizes the jaw members 110 and 120) may be coupled to a lead 2062 which supplies electrosurgical energy to the cutter 2000. Alternatively, the cutter 2000 may simply mechanically cut tissue 420.

As best illustrated in Fig. 38A, it is also envisioned that the cutter 2000 may include serrated cutting edges 2128a and 2128b to enhance cutting. Alternatively, it is also contemplated that the cutting edges 2028a and 2028b may be substantially dull and yet still cut the tissue 420 one sealed. For example, the cutter 2000 may include a spring-like actuator (not shown) which rapidly advances the cutting edges 2028a and 2028b (or 2022a and 2022b) through the tissue 420 with a predetermined force which is enough to cut the tissue 420 along the seal plane "B-B" or between two seals.

As best shown in Fig. 38B, the cutter may include a coating 2222 to facilitate cutting the tissue 420. The coating can include a resinous fluorine containing polymers or polytetrafluoroethylene commonly sold under the trademark Teflon® (or other Teflon-like substance) to facilitate mechanical cutting or may be an electrically conductive coating to facilitate electrosurgical cutting. Alternatively, the coating 2222 could also be electrically insulative in nature to reduce flashover or thermal spread during activation, or may be designed to reduce sticking. Many of these coatings are described in Applicants' co-pending earlier applications which are all incorporated by reference in their entirely herein, namely, U.S. Application Serial No. 10/116,944, PCT Application Serial No. PCT/US02/01890 and PCT Application Serial No. PCT/US01/11340.

As best illustrated in the comparison of Figs. 37A and 37B, the tube cutter 2000 is designed to longitudinally reciprocate along longitudinal axis "AA" to cut tissue 420 adjacent the jaw members 110 and 120 along the tissue seal plane "B-B". As can be appreciated, this typically requires re-grasping the tissue 420 such that the tissue sealing plane "B-B" is disposed on the cutting side of jaw members 110 and 120. Alternatively and as shown in Fig. 37B, the cutter 2000 may be designed to rotate in a cork-screw-like manner as it moves distally through the tissue 420. This may enhance the cutting process. It is also envisioned that a cutter 2000 may be designed such that the cutter 2000 is disposed within a recessed portion of one of the two jaw members, e.g., 110, such that the cutter 2000 simply rotates through the tissue 420 or around the jaw member 110 without moving along the longitudinal axis "AA" (or only moving minimally along axis "AA").

The tube cutter 2000 also includes an elongated channel 2040 disposed on the opposite side of the u-shaped blade 2020. The channel 2040 is necessary to facilitate unimpeded distal movement of the cutter 2000 over the jaw members 110 and 120 and allow the opposite (i.e., uncut) end of the tissue 420 to move freely proximally past the jaw members 110 and 120 during the cutting process. Alternatively, the cutter 2000 may be designed such that the cutter 2000 is generally arcuate or sleeve-like and is not tubular in fashion. This design also allows free proximal movement of the uncut tissue 420 end past the jaw members 110 and 120 during cutting.

Figs. 39A and 39B shows yet another embodiment of the forceps 3000 of the present disclosure wherein a unilateral jaw closure mechanism 3010 is utilized to grasp tissue 420. More particularly, the forceps 3000 includes a first or upper jaw member 3110 and a second or lower jaw member 3120 disposed at the distal end of an elongated shaft 3012. The unilateral closure mechanism 3010 is designed for use with laparoscopic, bipolar or monopolar electrosurgical devices as described herein.

The unilateral closure mechanism 3010 includes one stationary jaw member 3120 mounted to the shaft 3012 and pivoting jaw member 3110 mounted about a pivot pin 3160 attached to the shaft 3012. A reciprocating sleeve 3130 is disposed about the outer periphery of the shaft 3012 and is

preferably remotely operable by a user. The pivoting jaw 3110 includes a detent or protrusion 3140 which extends from jaw member 3110 through an aperture 3150 disposed within the outer sleeve 3130. The pivoting jaw 3110 is actuated by sliding the sleeve 3130 axially along the outside of shaft 3012 such that the aperture 3150 abuts against the detent 3140 on the pivoting jaw 3110. Pulling the sleeve proximally closes the jaw members 3110 and 3120 about tissue 420 grasped therebetween and pushing the sleeve 3130 distally open the jaw members 3110 and 3120 for approximation.

As best illustrated in Figs. 39B and 39C of the present disclosure, a blade or knife channel 3170 runs through the center of the jaw members 3110 and 3120 such that a blade 3190 can cut the tissue 420 grasped between the jaw members 3110 and 3120 only while the jaws are closed. More particularly, the blade 3190 can only be advanced through the tissue 420 when the jaw members 3110 and 3120 are closed thus preventing accidental or premature activation of the blade 3190 through the tissue 420. Put simply, the knife channel 3170 is blocked when the jaws members 3110 and 3120 are opened and aligned for activation when the jaw members 3110 and 3120 are closed. In addition, the unilateral closure mechanism 3010 can be structured such that electrical energy can be routed through the sleeve 3130 at the protrusion contact 3180 point with the sleeve 3130 or using a "brush" or lever (not shown) to contact the back of the moving jaw 3110 when the jaw closes. It is envisioned that the jaw member 3110 may be closed and energized simultaneously or independently by a separate actuator (not shown).

More particularly, when the sleeve 3130 is pushed distally, the proximal most portion of the aperture 3150 abuts against the protrusion to pivot the jaw member 3110 into the open configuration. Preferably, the point of contact 3155 between the aperture and the protrusion 3140 is insulated to prevent premature activation of the forceps 3000. When the sleeve is pulled proximally, the distal most portion of the sleeve abuts against the protrusion 3140 and closes the jaw member 3110. Preferably, the distal most contact 3180 and provides electrical continuity to the jaw members 3110 and 3120 through the sleeve 3130 for sealing purposes.

As can be appreciated, these designs provide at least two important safety features: 1) the blade 3190 cannot extend while the jaw members 3110 and 3120 are opened; and 2) electrical continuity to the jaw members 3110 and 3120 is made only when the jaws are closed.

It is envisioned that the moving jaw 3110 may also function as the blade 3190 with mechanical energy, electrical energy or a combination of both used for cutting. For example, the blade channel 3170 could include a mechanical cutting mechanism or an electromechanical cutting mechanism (as described elsewhere herein) which is separately actuated once the jaw members 3110 and 3120 are closed about the tissue 420. It is also envisioned that the sleeve 3130 may be biased against a spring assembly (not shown) to provide increased mechanical advantage during activation. It is contemplated that various mechanisms may be employed to provide a mechanical advantage to increase the closure force between jaw members 3110 and 3120, e.g., two, three and/or four-bar linkages, hydraulic mechanisms, electro-assisted actuators, cam mechanisms, gear assemblies, etc.

Another embodiment of the present disclosure includes the use of a hard anodized aluminum 3200 with or without the use of a synthetic sealed coating 3300 (See Figs. 39A and 39B) made from a resinous fluorine containing polymers or polytetrafluoroethylene commonly sold under the trademark Teflon® on electrically non-conductive components of one or both of the jaw members 3110 and 3120 (i.e., the areas surrounding the conductive surfaces) to control the electrical path between the two jaw members 3110 and 3120 during electrosurgical activation and reduce sticking. Other materials which tend to reduce tissue adherence include: nickel-chrome, chromium nitride, Ni200, Ni201, inconel 600, tin-nickel. It is envisioned that utilizing a hard anodized aluminum 3200 on at least one jaw member's 3110 non-sealing surface electrically isolates the jaw members 3110 and 3120 from one another and confines the electrosurgical energy between the conductive sealing surfaces. The non-stick coating 3300 reduces undesirable sticking of tissue 420 to jaw components during the sealing process.

Preferably, the hard anodized aluminum 3200 has a high dielectric strength and good wear properties and has a thickness of about 0.001 to about

0.003 inches. It has been found that electrically insulating the aluminum jaws 3110 and 3120 from other surrounding components confines the electrical path to between the jaw members 3110 and 3120 and eliminates alternate current paths which can result in collateral tissue damage.

Although the subject apparatus has been described with respect to preferred embodiments, it will be readily apparent to those having ordinary skill in the art to which it appertains that changes and modifications may be made thereto without departing from the spirit or scope of the subject apparatus.

Figs. 40A and 40B show another embodiment of the present disclosure wherein the instrument 4000 includes a multi-position handle assembly 4020, an endoscopic shaft 4012 and a rotation assembly 4080. Rotatable assembly 4080 is axially fixed and rotatable in relation to handle assembly 4020 in a known manner, e.g., as described above with respect to Figs. 1-39C. Endoscopic shaft 4012 is secured within rotatable assembly 4080 such that rotation of rotatable assembly 4080 in relation to handle assembly 4020 effects rotation of endoscopic shaft 4012. End effector assembly 100 is affixed to the end of shaft 4012 as described above.

The handle assembly 4020 includes a generally T-shaped handle portion 4050 which includes a first fixed grip 4050a and a second fixed grip 4050b. The first fixed grip 4050b is generally axially-aligned with a longitudinal axis "AA" disposed through the instrument 4000. As will be explained in more detail below, this facilitates gripping and manipulating the instrument 4000 in-line, e.g., when disposed through a vertically oriented cannula (not shown). The second fixed grip 4050b is generally transversally-aligned with the longitudinal axis "AA" disposed through the instrument 4000 preferably at an angle of about ninety degrees (90^0). As will be explained in more detail below, this enables the user to grip and manipulate the instrument in a pistol-like manner.

A first actuating handle 4040a is disposed generally adjacent to the first grip 4050a and is mounted within the handle assembly for movement between a first, distal-most position which allows the surgeon to position and approximate tissue between jaw members 110 and 120 (See Fig. 20) to a more proximal position which allows a surgeon to engage and grasp tissue between opposing jaw members 110 and 120 (See Fig. 26). The interworking

relationships of the various internal components associated with movement of the jaw members 110 and 120 to approximate and grip tissue is explained in more detail above. First actuating handle 4040a cooperates with fixed grip 4050a to facilitate handling and actuation of the of the instrument 4000 in a pistol-like manner. As can be appreciated, handling the instrument in the pistol-like position facilitates repositioning the instrument trajectory within the surgical area in the Z-plane and facilitates axial rotation about the longitudinal axis "AA" (i.e., rotation along the Z-plane and about the X-axis).

A second actuating handle 4040b is disposed generally adjacent to the second grip 4050b and is mounted within the handle assembly for movement between a first position which allows the surgeon to position and approximate tissue between jaw members 110 and 120 (See Fig. 20) to a second position which is closer to grip 4050b which allows a surgeon to engages and grasps tissue between opposing jaw members 110 and 120 (See Fig. 26). Second actuating handle 4040b cooperates with fixed grip 4050b to facilitate handling and actuation of the of the instrument 4000 in a longitudinally-aligned manner. As can be appreciated, handling the instrument in the longitudinally-aligned position facilitates repositioning the instrument trajectory within the Y and Z planes of the surgical area (i.e., orbital motion along the Y and Z planes and about the X-axis).

As best shown in Fig. 40B, first and second actuating handle 4040a and 4040b are commonly joined by an actuating link 4075 which permits the surgeon to use either actuating handle 4040a and 4040b to actuate the above-mentioned interworking components of the drive assembly to approximate and close the jaw members 110 and 120 about tissue 420. It is also envisioned to utilize a combination of the actuation handles 4040a and 4040b to facilitate orientating the instrument 4000 within the operating cavity and grasping tissue 420.

Handle assembly may also include a series of thumb guides or thumb rests 4090a and 4090b which position the surgeon's thumb in opposition to actuating handles 4040a and 4040b, respectively, during handling and actuation of the instrument 4000 (see Fig. 40A). More particularly, thumb rest 4090a includes an aperture 4092a defined therein which positions the

surgeon's thumb when utilizing the instrument 4000 in the pistol-like fashion and thumb rest 4090b includes an aperture 4092a defined therein which positions the surgeon's thumb in when utilizing the instrument 4000 in the longitudinally-aligned fashion.

As best shown in Fig. 40A, the instrument 4000 also includes a set of first and second triggers 4070a and 4070b which each activate the knife assembly 200. The interworking components and of the knife assembly and their cooperative movements are described in detail above with respect to Figs. 16, 21-30 and 34A-34C. First trigger 4070a is disposed generally adjacent to actuating handle 4040a such that a surgeon can easily and selectively activate the trigger 4070a utilizing one of his/her fingers, e.g., index finger. As mentioned above with respect to Figs. 21-30, proximal movement of the trigger 4070a moves the knife 205 through the tissue 420 in a distal motion to sever the tissue 420 along the ideal tissue cutting plane "B-B" (See Figs. 27-30). Releasing the trigger 4070a rests the knife 205 for the next (or additional) cutting purposes.

Second trigger 4070b is preferably located near the proximal-most portion of the handle assembly 4020. Trigger 4070b is positioned for use with the instrument 4000 when being used in a longitudinally-aligned fashion. Unlike the trigger 4070a, trigger 4070b is a push button trigger which moves the knife 205 through the tissue 420 in a distal motion upon activation (i.e., forward push-button movement towards handle assembly 4020). Trigger 4070b is also preferably located adjacent thumb rest 4090b which enables to the surgeon to easily activate the knife 205 with his/her thumb once the tissue 420 is properly positioned between jaw member 120 and 120.

Triggers 4070a and 4070b are both mechanically connected to the knife assembly 200 such that either trigger 4070a and 4070b may be utilized by the surgeon depending upon a particular orientation of the instrument or depending upon a particular purpose. Moreover, either trigger may be utilized when utilizing either actuating handle 4040a or 4040b.

It is envisioned that the aforedescribed multi-position instrument 4000 and handle 4020 may be utilized with either open or endoscopic procedures. In addition, the handle design 4020 may be utilized with other surgical instruments

for accomplishing other surgical procedures, e.g., the end effector assembly 100 assembly may include staplers, graspers, vessel dissection and/or coagulation tools, or any other tool assemblies currently available which require hand actuation. Moreover, the materials used to construct the individual components of the device may be chosen from a variety of known materials to achieve the desired result. In addition, the handle 4020 may be designed to include a variety of ergonomically pleasing features to enhance the overall "feel" of the instrument during handling and use. For example, the handle 4020 may include a variety of scallops or curves which contour to the user hand during surgery. In addition, the handle may include rubber-like surfaces to enhance the user's grip during use.

It is also envisioned that the thumb rests 4090a and 4090b may be made from a thin, soft rubber material which deforms if the user prefers not to utilize the thumb rest during surgery. In this case, the user simply grips the handle in a conventional fashion which, in turn, folds or deforms the thumb rest into a recessed area on the outer surface of the handle. It is also envisioned that the thumb rests 4090a and 4090b may be selectively removable from the handle 4020 if desired and/or may come as separate attachments to the handle 4020.

As mentioned above, manufacturing an instrument which provides appropriate closure force between opposing electrode within the preferred pressure range of about 3 kg/cm^2 to about 16 kg/cm^2 is often difficult especially due to the inherent difficulties of accurately determining the closure force between the jaw members 110 and 120 after assembly. As can be appreciated, relying on a surgeon to manually provide the appropriate closure force within the appropriate range on a consistent basis would be difficult and the resultant effectiveness and quality of each seal would vary. For example, one of the inherent difficulties of accurately measuring the closure force includes measuring the closure force in a non-destructive fashion (i.e., placing a measuring device, such as a strain gauge or pressure sensitive film, between the jaw members 110 and 120 interferes with the final angle of the jaw members, interfering with the measurement). The measurement device would need to be shaped exactly like the jaw profile in order to measure the pressure

accurately. The jaw would have to be free of stop members or only the peaks in pressure would be measured.

Moreover, it has been found that manufacturing tolerances of the internal working components of the handle assembly and actuating assemblies can greatly effect the overall closure pressure between the sealing surfaces. For example, with the above-described four-bar mechanical linkage (i.e., movable handle 40, a link 65, a cam-like link 36 and a base link embodied by fixed handle 50 and a pair of pivot points 37 and 67b - See Fig. 13) which operates to compress the spring 22, it has been found that minor inconsistencies with the each linkage can effect the overall compressed length of the spring 22 which will yield a different closure pressure. Moreover, inconsistencies with the other interworking elements of the handle assembly 30, the drive assembly 21 and the cam link 36 may also effect the overall compressed length of the spring 22 to yield a different closure pressure.

The presently disclosed method provides a simple and effect technique for verifying that after assembly the forceps is capable of providing a desired closure force between jaw members 110 and 120 within a desired working range for effective vessel sealing. The method includes the steps of: specifying a desired closure pressure range for effective tissue sealing; manufacturing each jaw member 110 and 120 such that specifications of each jaw member 110 and 120 fall within an acceptable manufacturing range, the specifications being selected from the group consisting of: surface area of each jaw member 110 and 120, distance from a pivot (i.e., pivot recess 175 - see Fig. 14) of each jaw member 110 and 120 to a centroid of a sealing surface 114 and 124 of each jaw member; angle between a cam slot 172 and 174 of each jaw member 110 and 120 and a line perpendicular to the sealing surface 114 and 124 of each jaw member 110 and 120; distance from the cam slot 172 and 174 to the pivot 175 of each jaw member 110 and 120; and a width of the cam slot 172 and 174 of each jaw member 110 and 120; providing a spring 22 with a known spring constant and known free length; activating the forceps 10 that engage tissue 400; and measuring the compressed length of the spring 22 to verify that the closure pressure falls within specified range.

For example and as best shown in Fig. 41, to obtain a closure pressure of 8.5 kg/cm^2 within an acceptable range of +30% and -15% (i.e., 7.225 kg/cm^2 to 11.05 kg/cm^2) the end effector 100 specifications and the spring 22 specifications are measured to be within the following ranges: surface area of jaw (SA) = .156 in^2; distance from jaw pivot to centroid of jaw seal surface (¢) = .693 inches +/- .005 inches; angle between cam slot and a line perpendicular to seal surface (β) = 30^0 +/- 1^0; distance from cam slot to pivot (CS-P) = .156 inches +/- .002 inches; width of slot (SW) = .065 inches +/- .001 inches; spring constant = 325 lb/in +/- 10%; spring free length = 1.250 inches +/- .010 inches. After determining that the jaw assembly specifications and the spring specifications fall within the above preferred ranges, the compressed length of the spring 22 is measured to verify that the closure pressure falls within the above range.

It is envisioned that the forceps may include a visual or audible indicator (not shown) to allow easy and accurate verification of the compressed spring length for verification purposes. For example, a color guide or tab (not shown) may be associated with the spring 22 such that the compressed spring length is shown on the outside of the handle assembly 20. To verify a preferred closure pressure, a user simply actuates the forceps 10 to determine that the compressed length of the spring 22 is within the correct range. Alternatively, a series of graduations or table may be included on the outside of the handle assembly to visually correlate closure pressure with compressed length of the spring 22.

While several embodiments of the disclosure have been shown in the drawings, it is not intended that the disclosure be limited thereto, as it is intended that the disclosure be as broad in scope as the art will allow and that the specification be read likewise. Therefore, the above description should not be construed as limiting, but merely as exemplifications of preferred embodiments. Those skilled in the art will envision other modifications within the scope and spirit of the claims appended hereto.

WHAT IS CLAIMED IS:

1. A bipolar forceps, comprising:

a shaft having opposing jaw members at a distal end thereof;

a drive assembly for moving said jaw members relative to one another from a first position wherein the jaw members are disposed in spaced relation relative to one another to a second position wherein the jaw members cooperate to grasp tissue therebetween;

a handle having:

a first gripping portion and a first movable actuator for independently actuating said drive assembly to move said jaw members;

a second gripping portion and a second movable actuator for independently actuating said drive assembly to move said jaw members;

a source of electrical energy connected to each jaw member such that the jaw members are capable of conducting energy through tissue held therebetween to effect a tissue seal;

a selectively advanceable knife assembly for cutting tissue along the tissue seal.

2. A bipolar forceps according to claim 1 wherein holding the forceps in a first position facilitates activation of said first movable actuator and holding the forceps in a second position facilitates activation of said second movable actuator.

3. A bipolar forceps according to claim 2 wherein the forceps includes a first trigger for advancing said knife assembly when said forceps is held in the first position and a second trigger for advancing said knife assembly when the forceps is held in said second position.

4. A bipolar forceps according to claim 2 wherein the forceps includes a first and second thumb rests which facilitate handling the forceps when the forceps is held in said first and second positions, respectively.

5. A bipolar forceps according to claim 4 wherein said thumb rests are made from a deformable material.

6. bipolar forceps according to claim 4 wherein said thumb rests are selectively removable from the forceps.

7. A bipolar forceps according to claim 3 wherein at least one of said triggers includes a push button.

8. A bipolar forceps according to claim 1 wherein the forceps includes at least one link member which connects the first and second movable actuators.

9. A bipolar forceps according to claim 1 wherein the forceps includes a rotating assembly for rotating the jaw members about a longitudinal axis defined through said shaft.

10. A method for verifying the closure pressure between jaw members of a forceps, the method comprising the steps of:

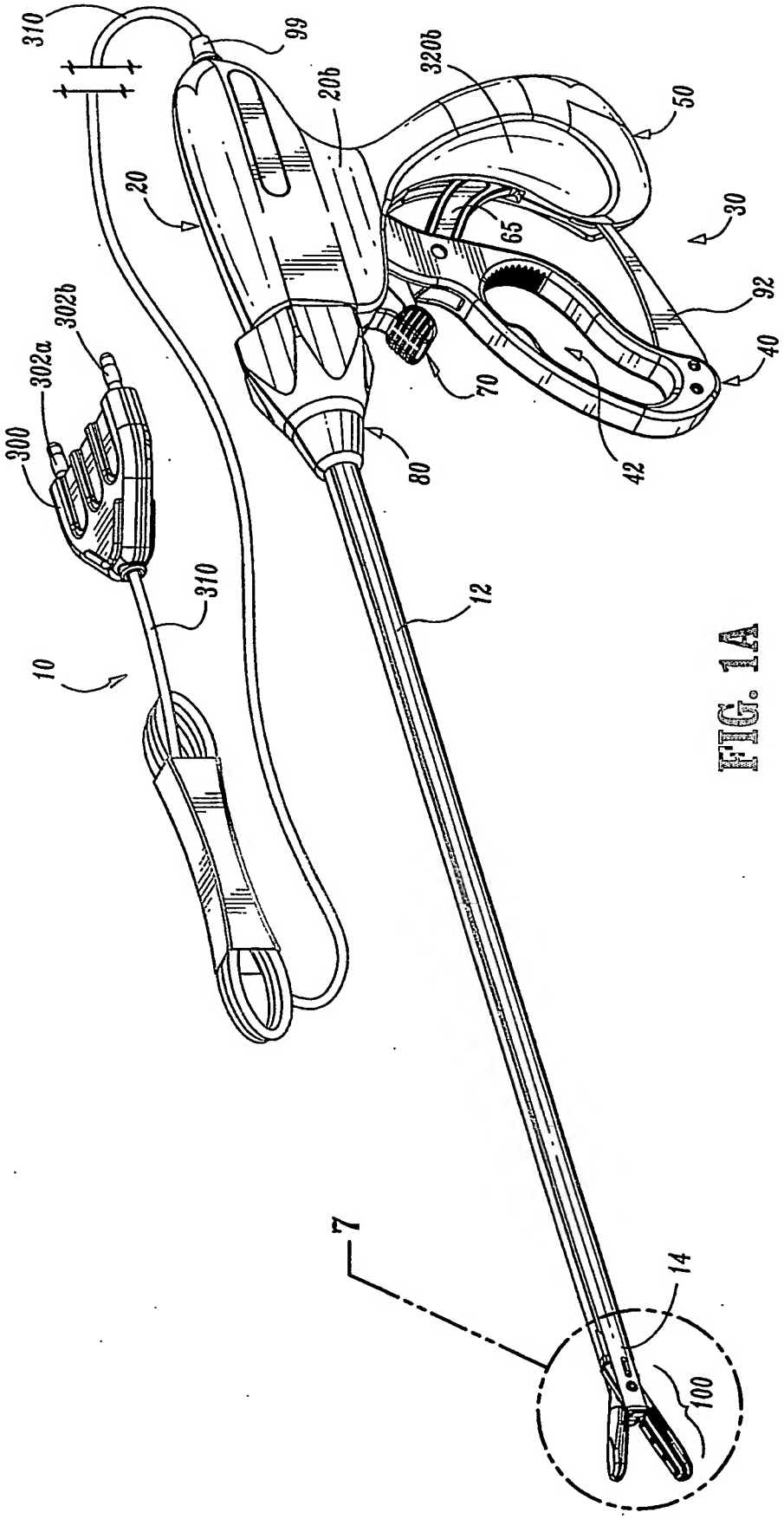
specifying a desired closure pressure range for effective tissue sealing;

manufacturing each jaw member such that specifications of each jaw member fall within an acceptable manufacturing range, the specifications being selected from the group consisting of: surface area of each jaw member, distance from a pivot of each jaw member to a centroid of a sealing surface of each jaw member; angle between a cam slot of each jaw member and a line perpendicular to the sealing surface of each jaw member; distance from the cam slot to the pivot of each jaw member; and a width of the cam slot of each jaw member;

providing a spring with a known spring constant and a known free length;

activating the forceps the engage tissue; and

measuring the compressed length of the spring to verify that the closure pressure falls within specified range.


310
99
320b
20b
50
20
30
65
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302b
302a
40
70
300
80
42
310
12
10
7
14
100

FIG. 1A

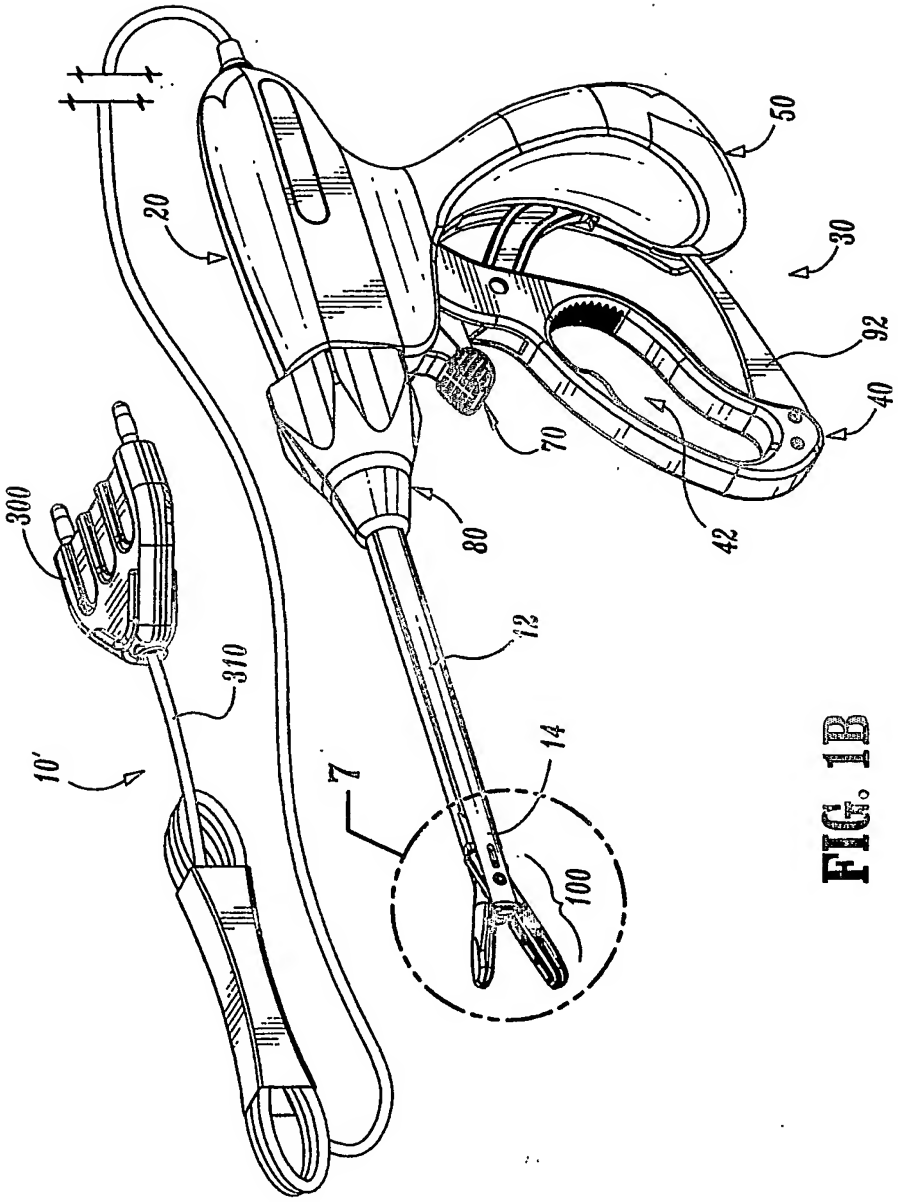


FIG. 1B

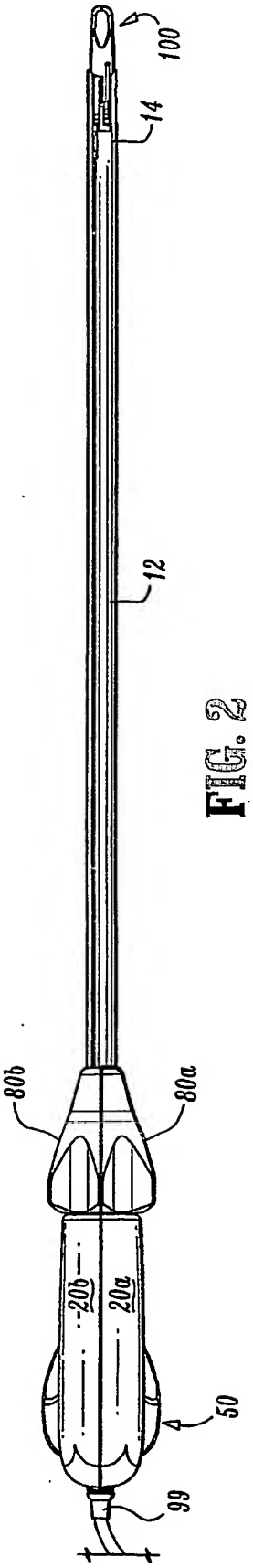

100
14
12
80b
80a
20b
20a
50
99

FIG. 2

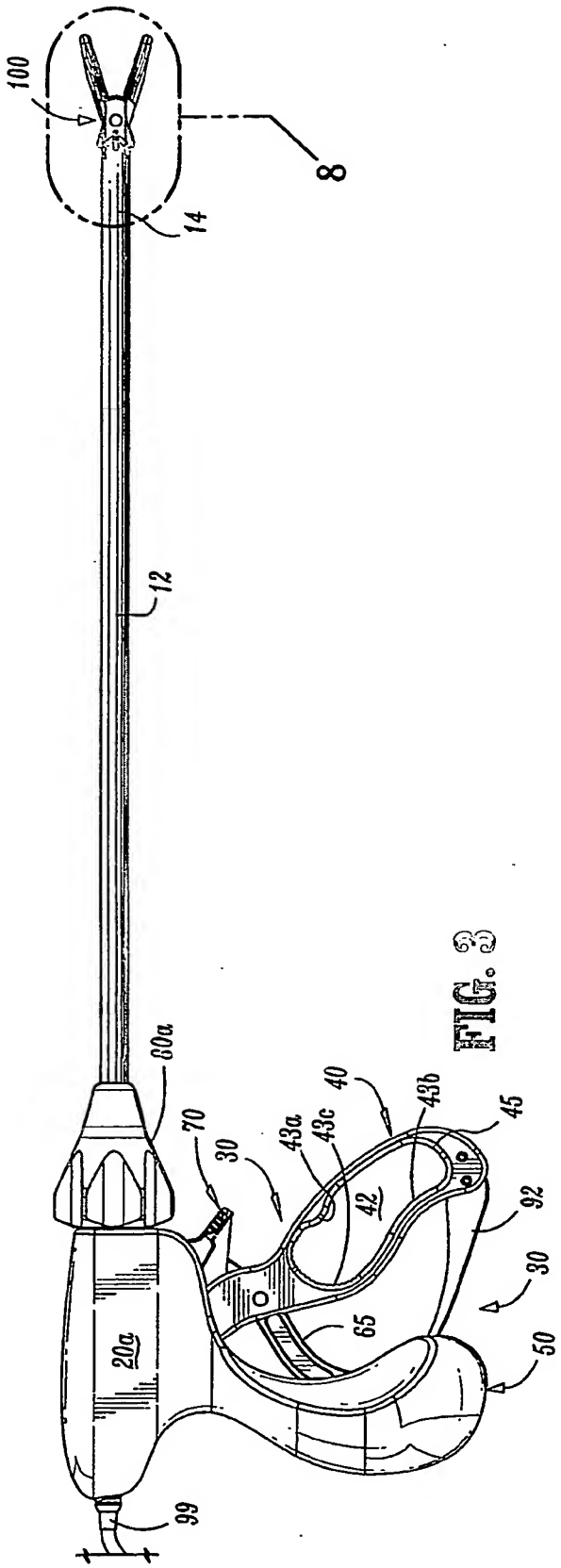

100
8
14
12
60a
70
30
43a
43c
40
43b
45
42
92
30
65
50
20a
99

FIG. 3

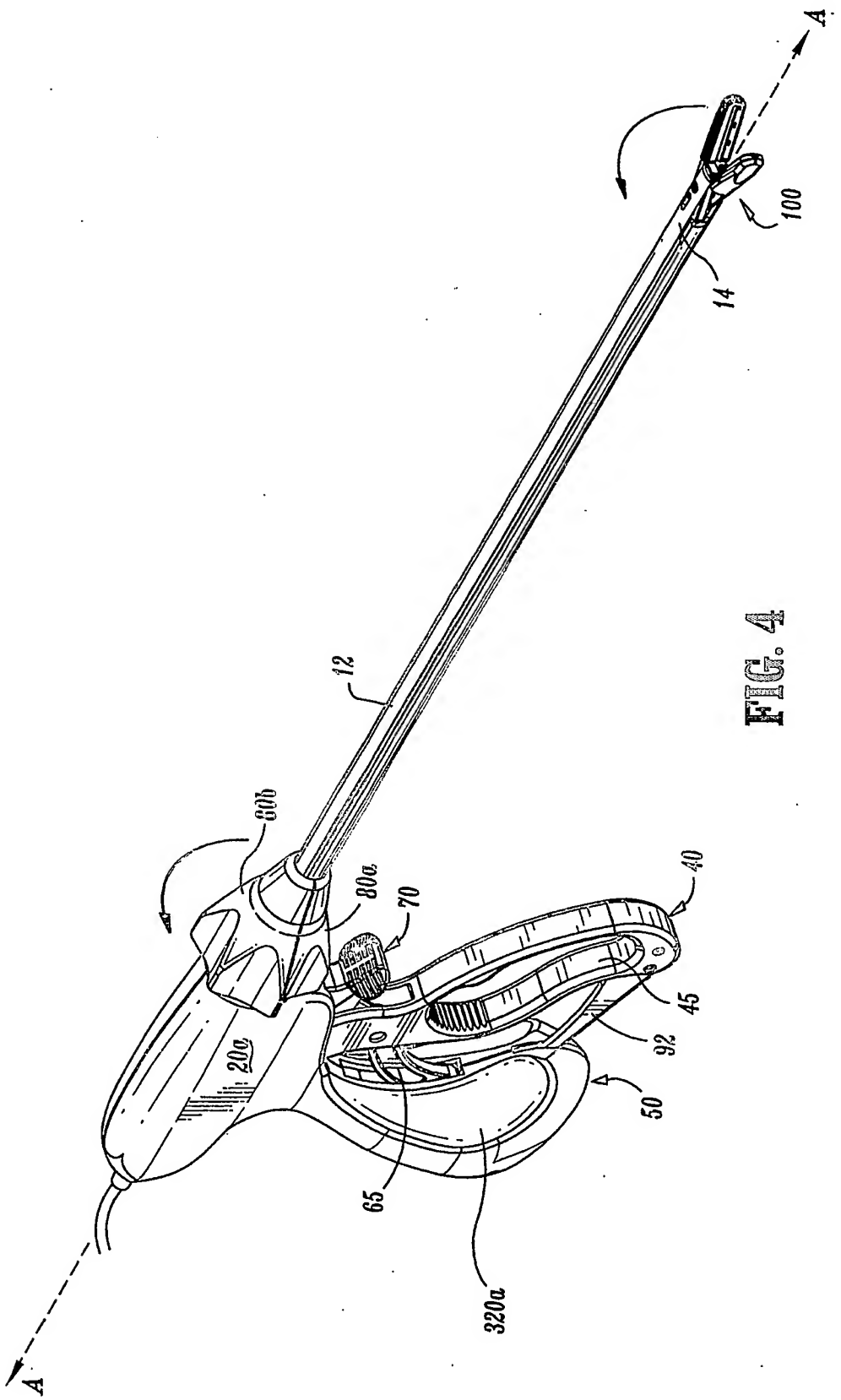


FIG. 4

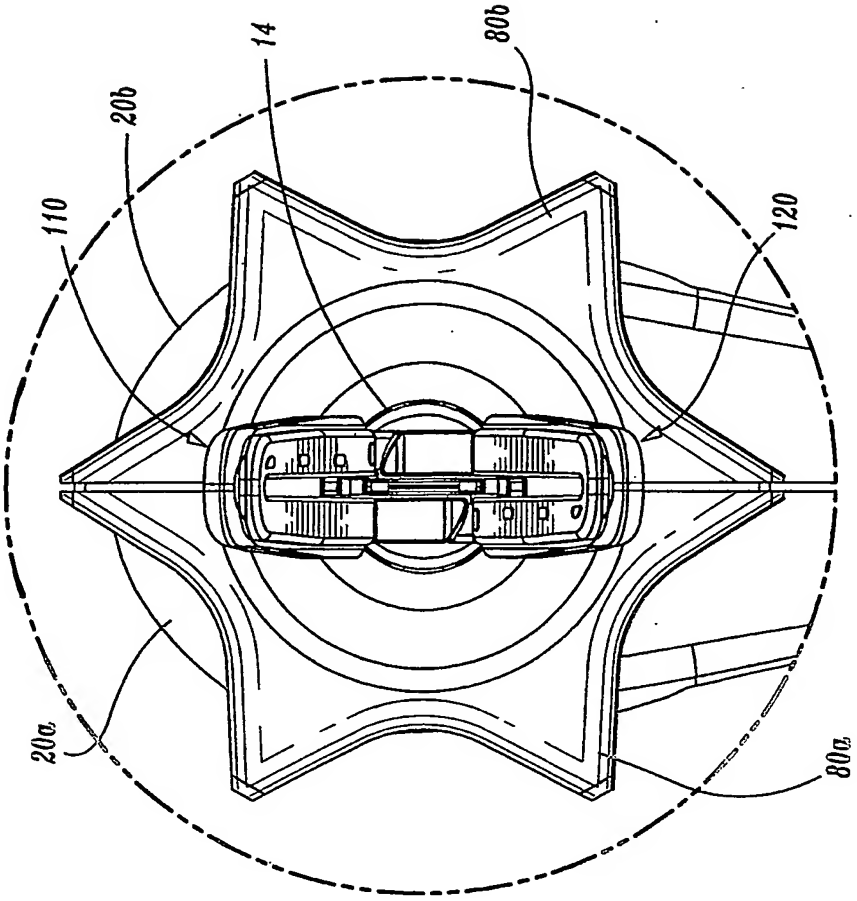

14
80b
20b
110
120
20a
80a

FIG. 6

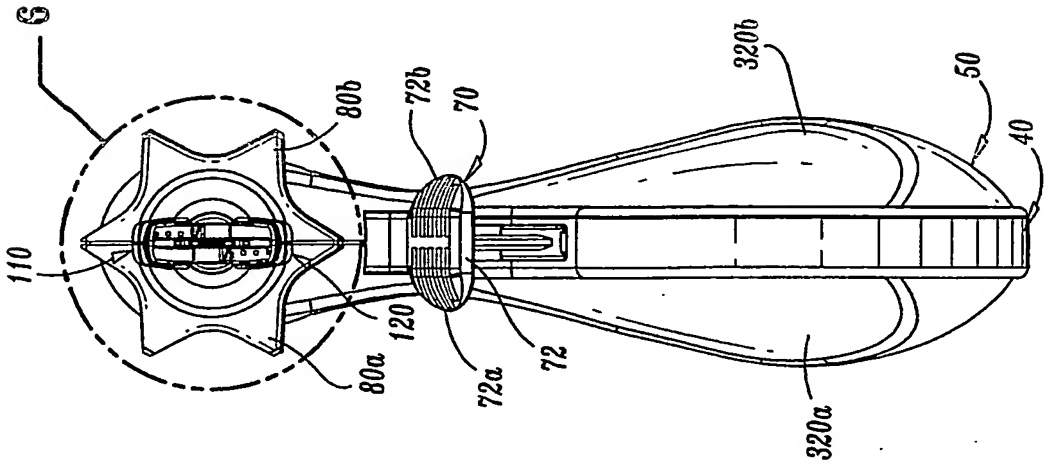

6
80b
72b
70
320b
50
40
110
120
80a
72a
72
320a

FIG. 5

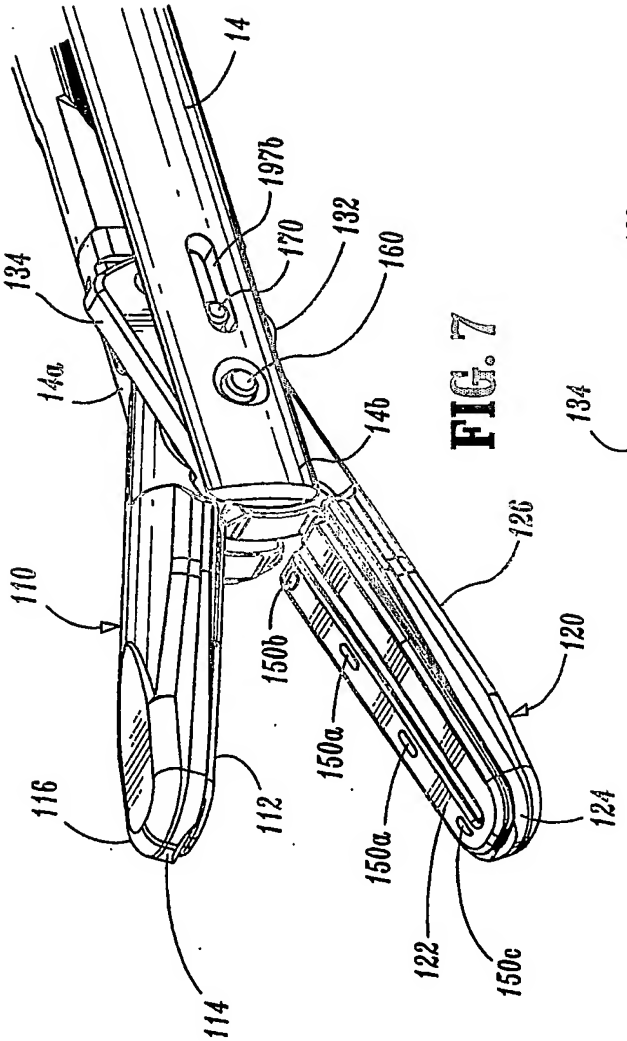
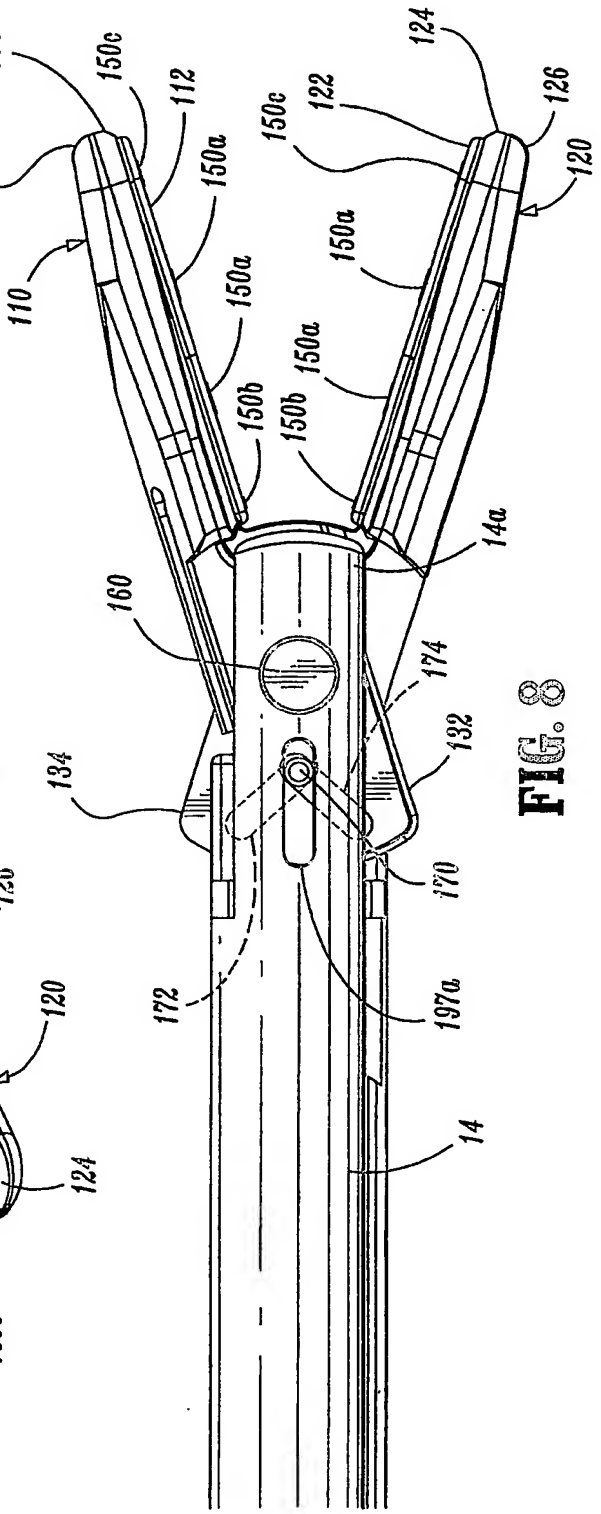

14
197b
170
132
160
134
14a
14b
110
126
150b
120
150a
116
112
150a
124
150a
122
150c
114

FIG. 7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150c
112
116
150a
110
150a
150b
150a
150b
150a
150c
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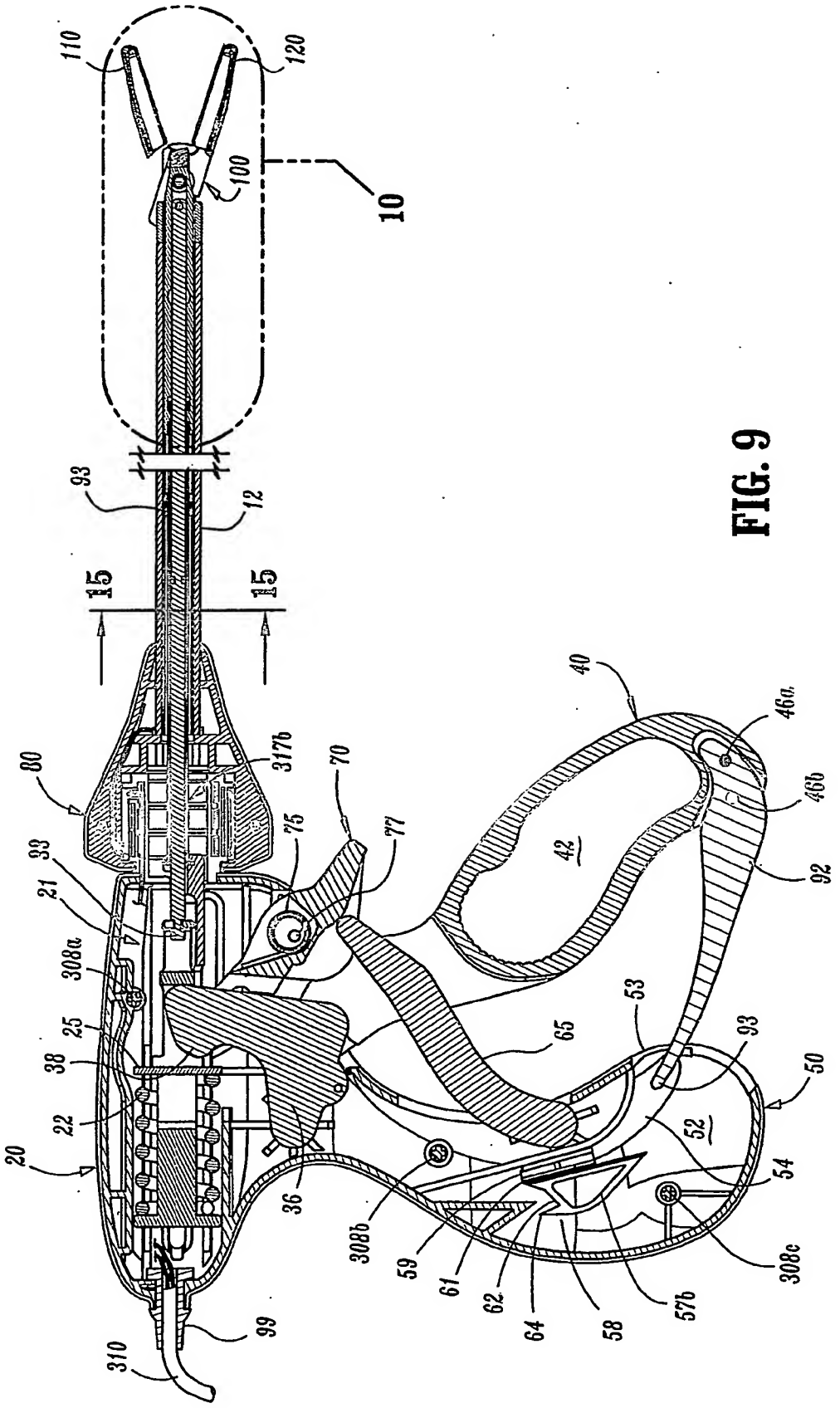
124
126
120
14a
160
174
132
134
170
172
197a
14

FIG. 8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120
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10
93
12
15
15
80
3176
70
75
77
33
21
308a
25
38
22
20
36
308b
59
61
62
64
58
576
65
53
93
50
52
54
308c
40
46a
46b
92
42
99
310

FIG. 9

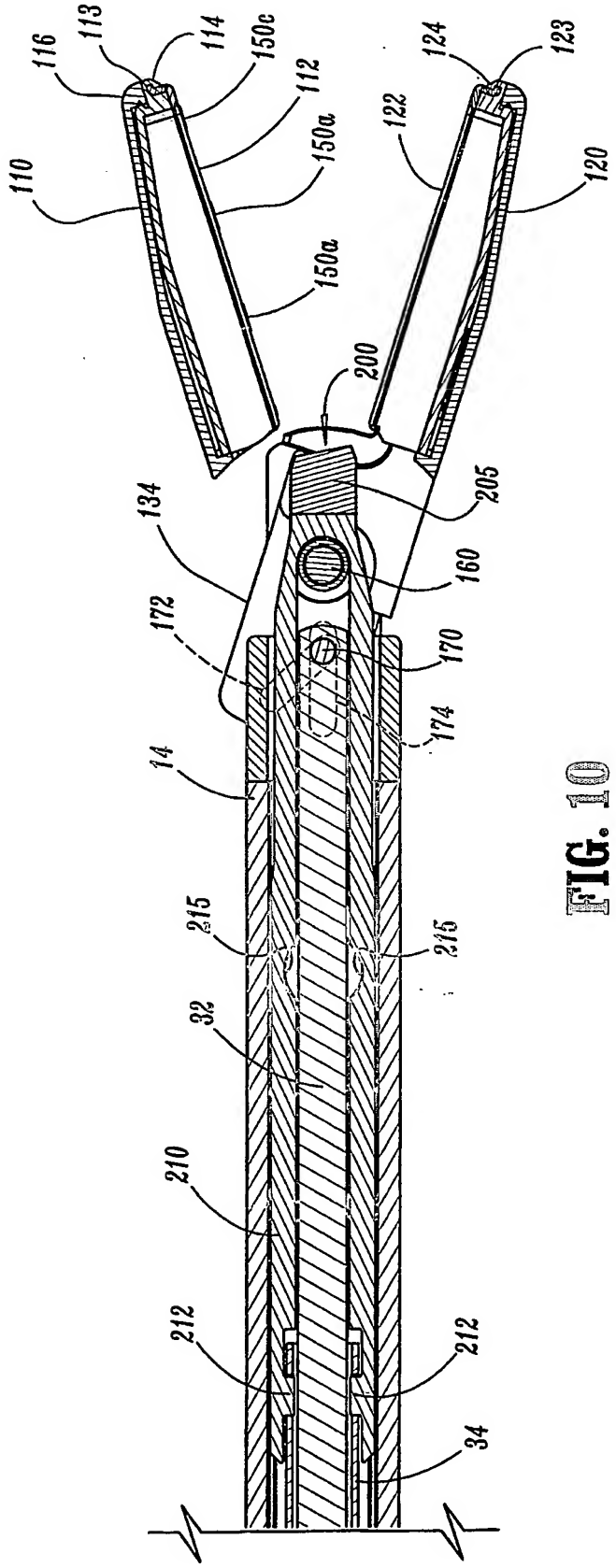
116
113
114
150c
112
150a
110
150a
124
123
122
120
200
205
134
160
172
170
174
14
215
215
32
210
212
212
34

FIG. 10

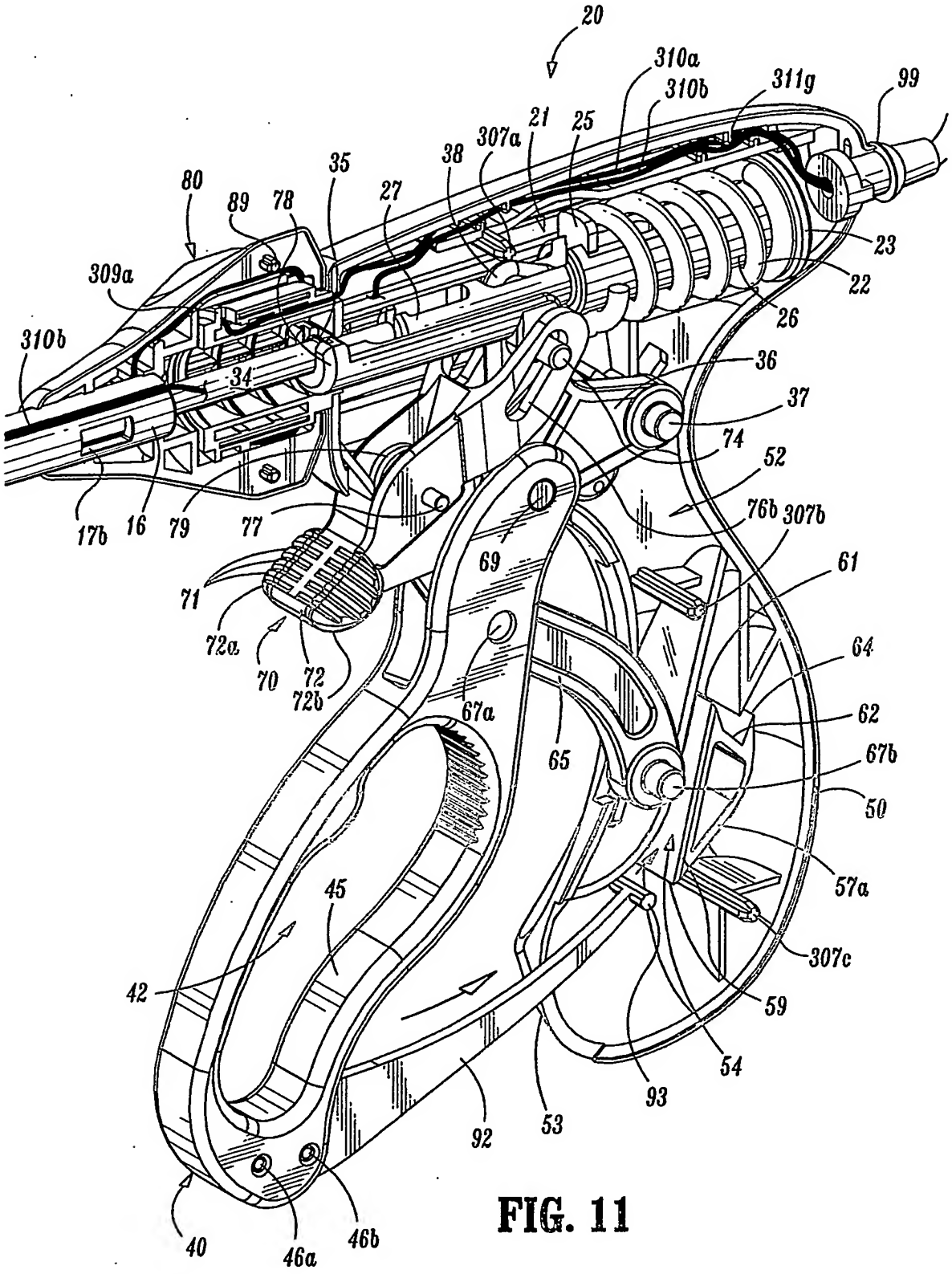
20
310a
310b
311g
99
21
25
307a
38
35
27
80
89
78
309a
23
22
26
36
37
74
52
76b
307b
61
64
62
67b
50
57a
307c
59
54
93
53
92
42
45
40
46a
46b
67a
65
69
71
72a
70
72
72b
17b
16
79
77
34

FIG. 11

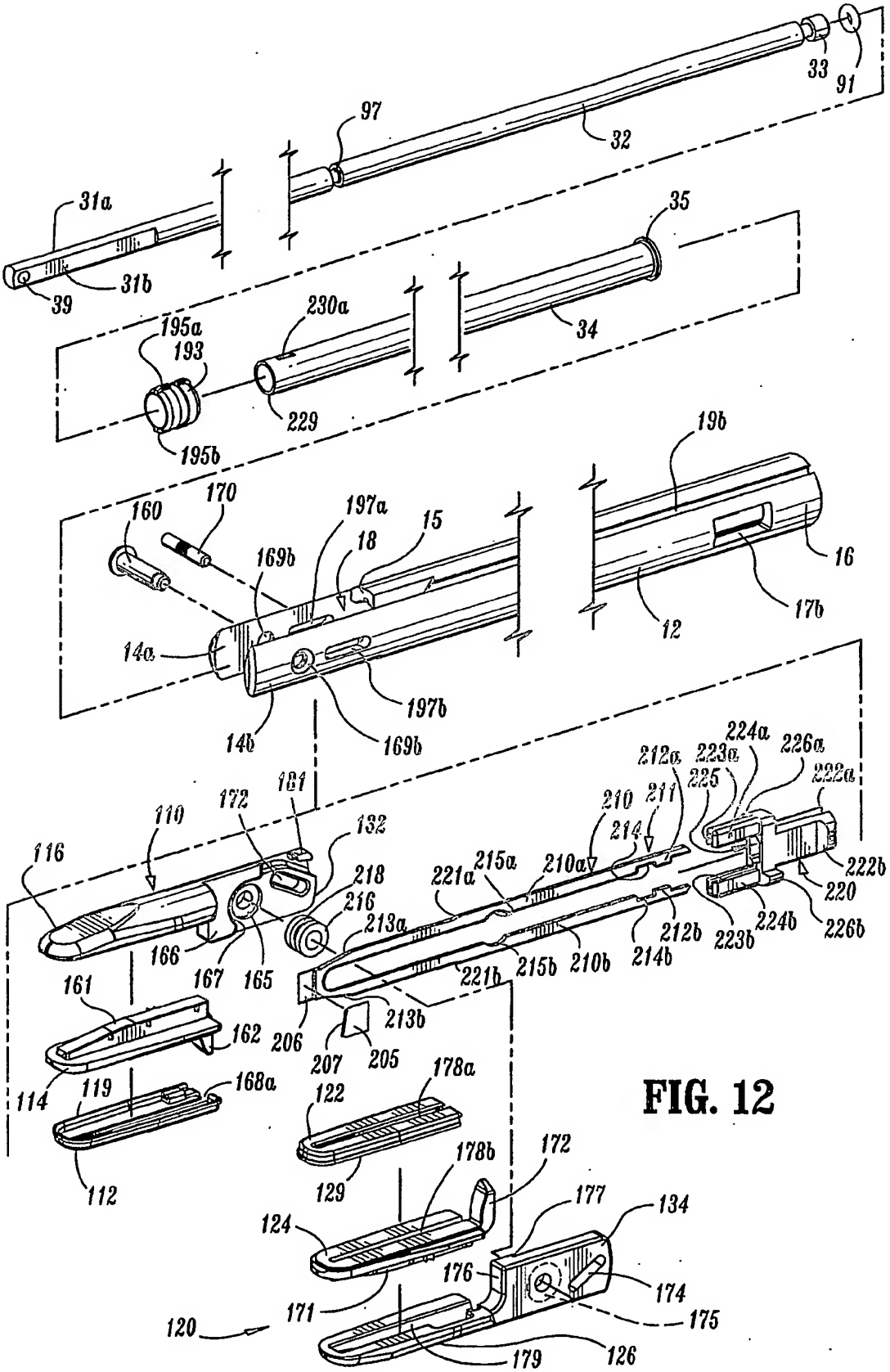
33
91
97
32
31a
35
31b
39
230a
195a
193
34
229
195b
19b
160
170
197a
15
18
169b
16
14a
17b
12
197b
14b
169b
224a
212a
223a
226a
225
222a
211
210
214
110
172
181
132
116
218
221a
215a
210a
222b
216
220
213a
212b
223b
224b
226b
166
167
165
221b
215b
210b
214b
161
213b
162
206
207
205
178a
114
119
168a
122
112
129
178b
172
177
134
124
176
174
171
175
120
179
126

FIG. 12

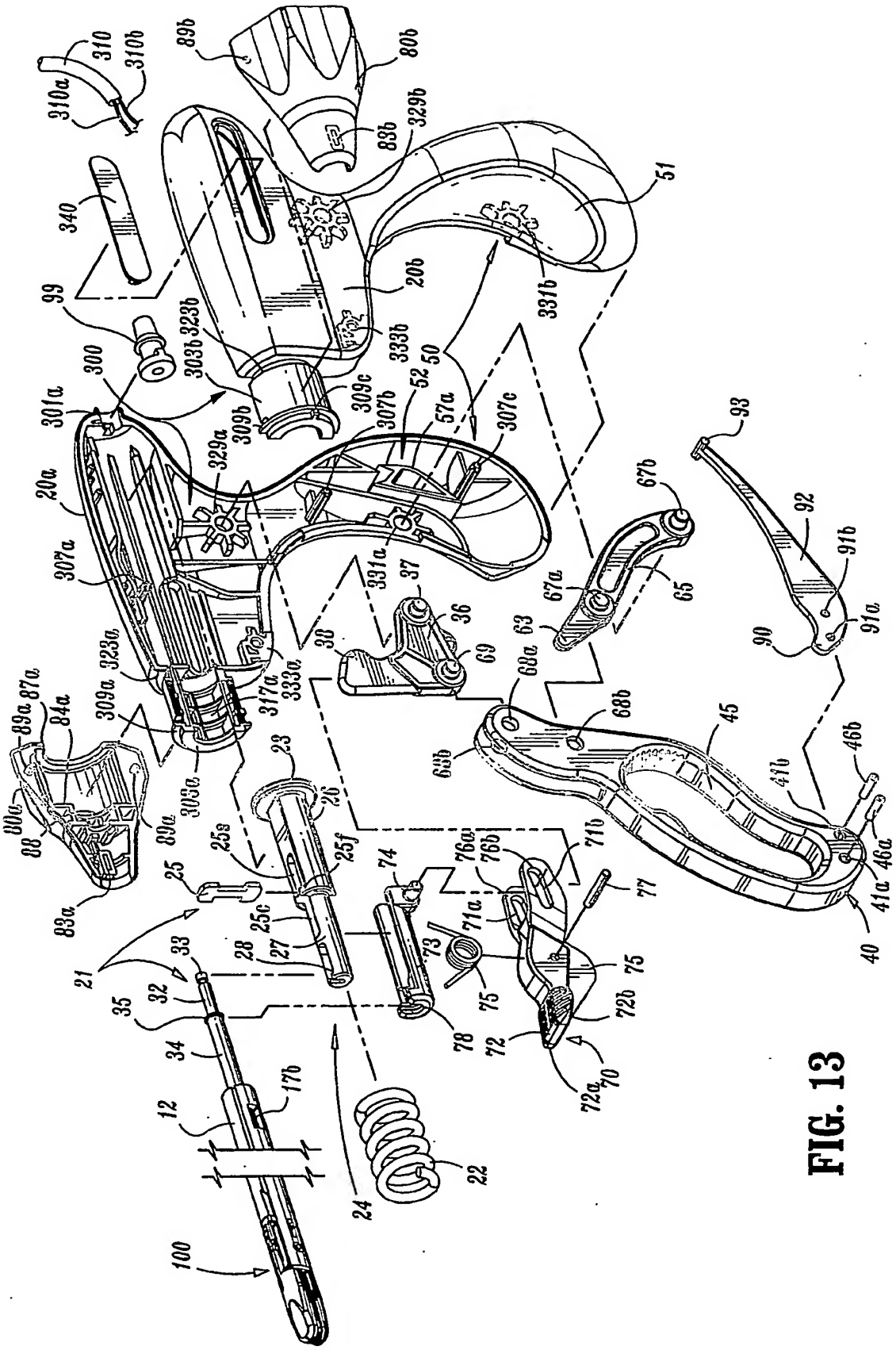
310
310b
310a
89b
80b
340
83b
329b
51
99
206
331b
323b
303b
333b
50
52
300
301a
309c
307b
57a
307c
329a
309b
20a
307a
331a
37
36
38
69
323a
309a
317a
333a
303a
23
26
25s
25f
25
25c
27
28
33
32
35
34
12
17b
21
24
22
100
74
76a
76b
71b
77
71a
73
75
78
72
72b
72a
70
67b
67a
65
63
68a
68b
68b
45
93
92
91b
91a
90
46b
41b
46a
41a
40
89a
87a
84a
80a
88
83a

FIG. 13

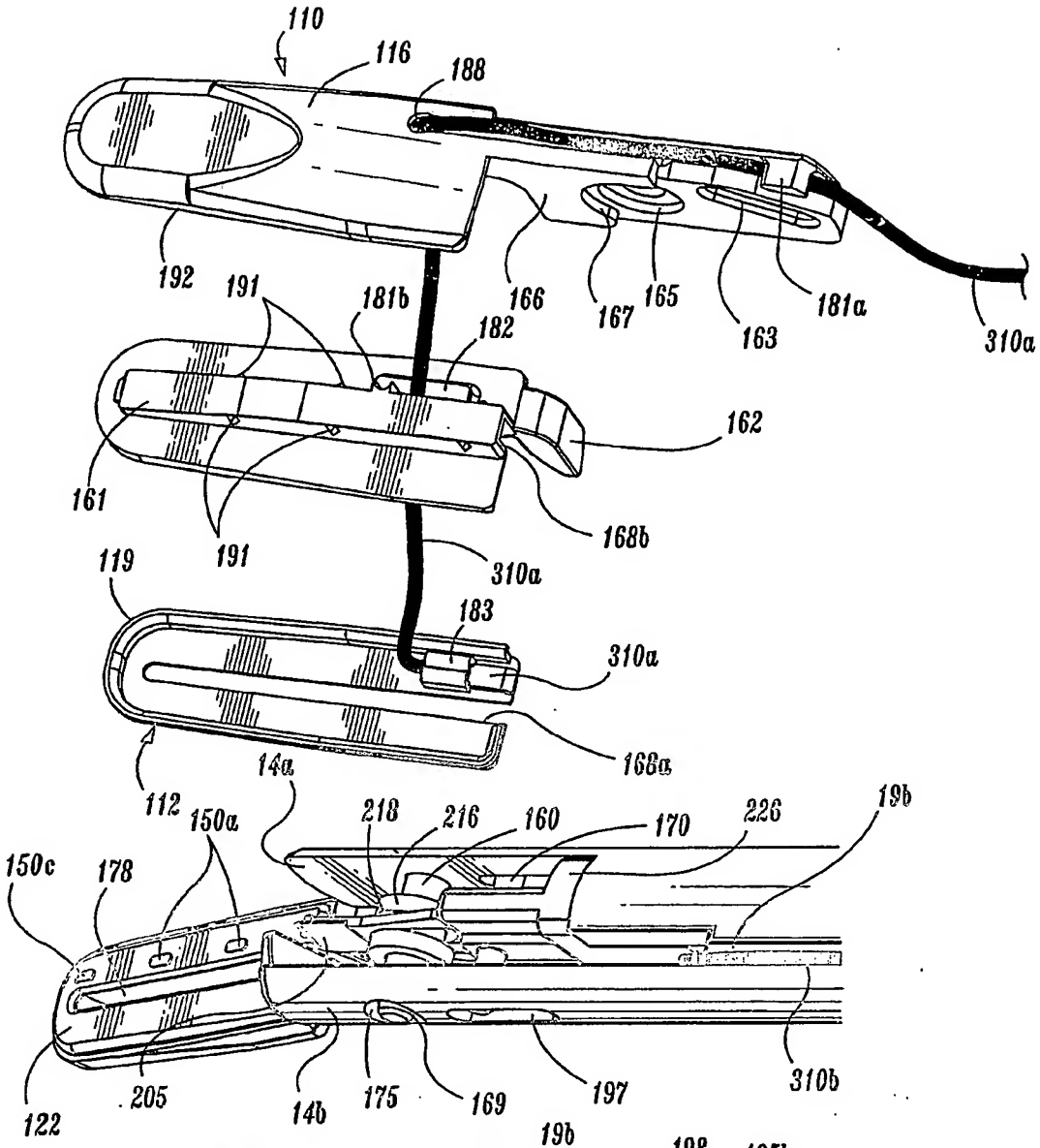
110
116
188
192
191
181b
166
167
165
163
181a
310a
182
162
161
191
168b
119
310a
183
310a
168a
112
14a
150a
218
216
160
170
226
19b
150c
178
205
14b
175
169
197
310b
122

FIG. 14

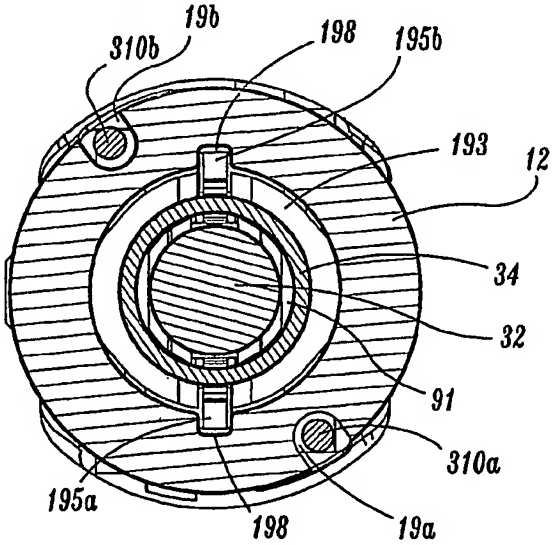
19b
310b
198
195b
193
12
34
32
91
310a
195a
198
19a

FIG. 15

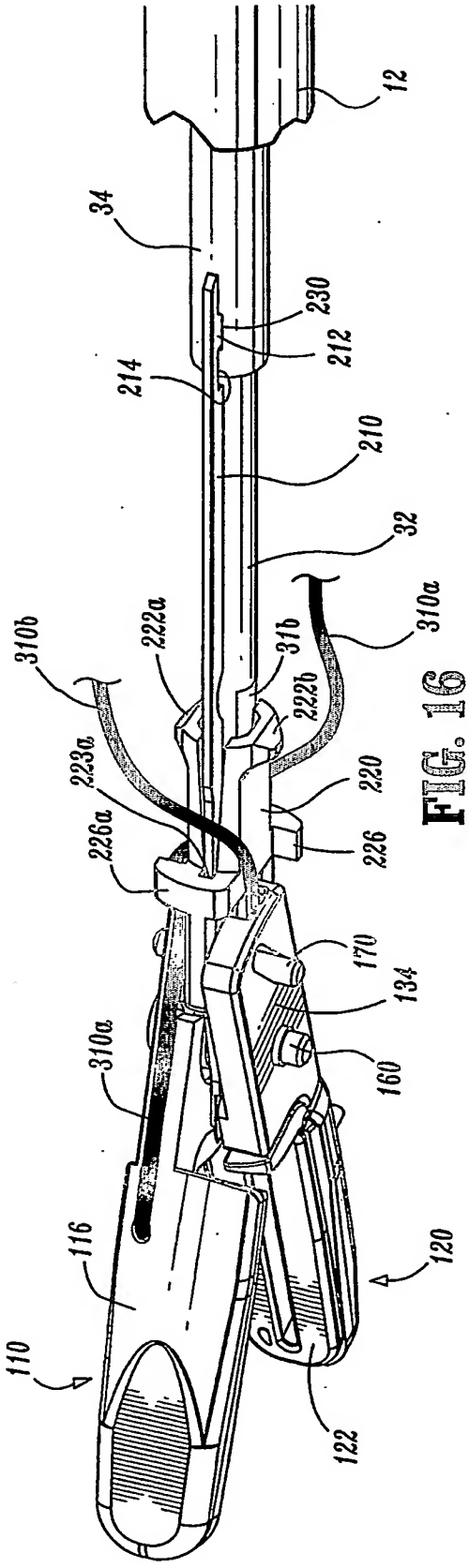
12
34
230
212
214
210
32
310b
222a
310a
31b
222b
223a
220
226a
226
170
134
310a
160
116
120
110
122

FIG. 16

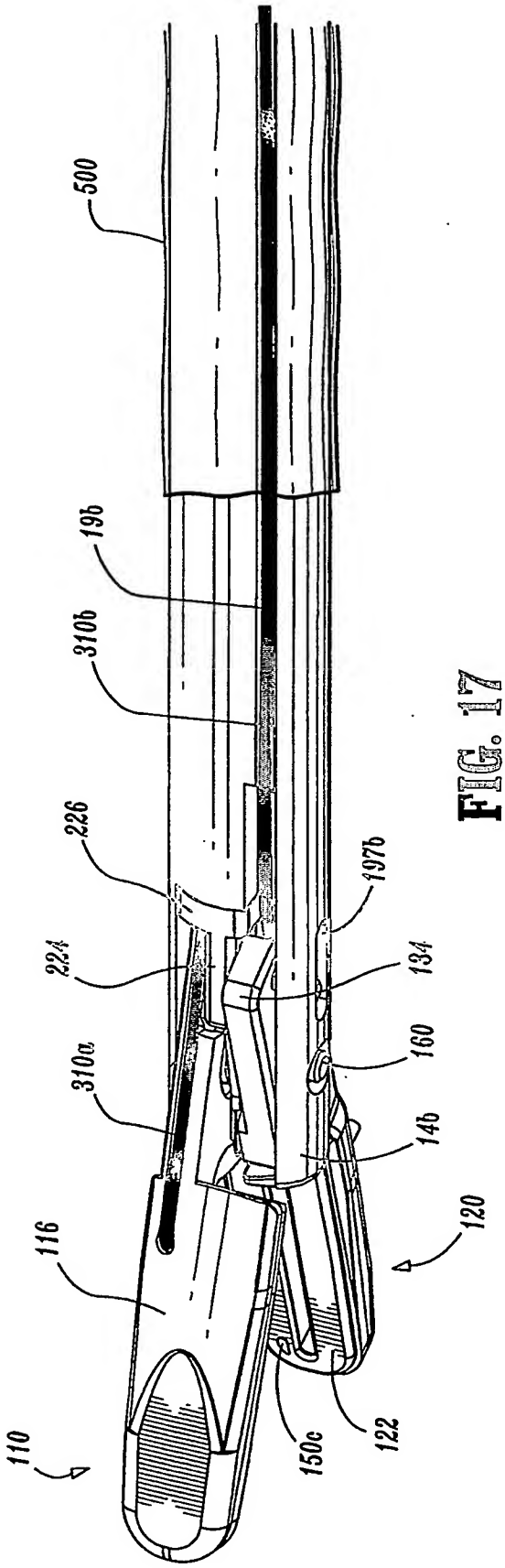
500
19b
310b
226
197b
224
134
310a
160
14b
116
120
110
150c
122

FIG. 17

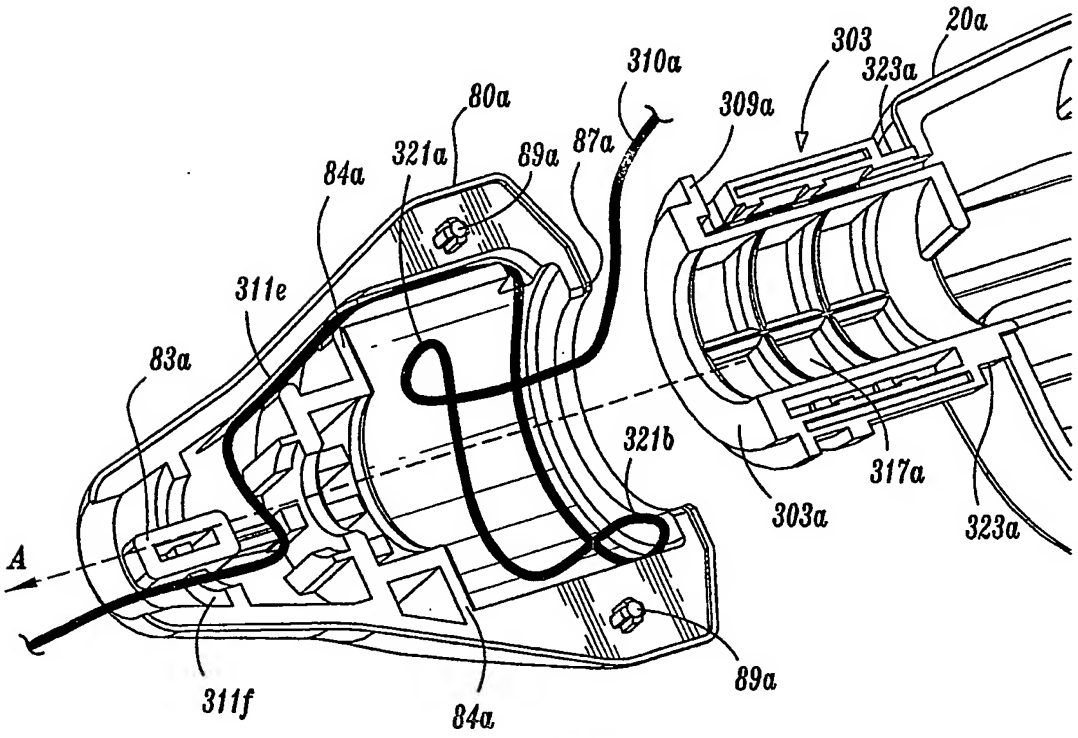

FIG. 18A

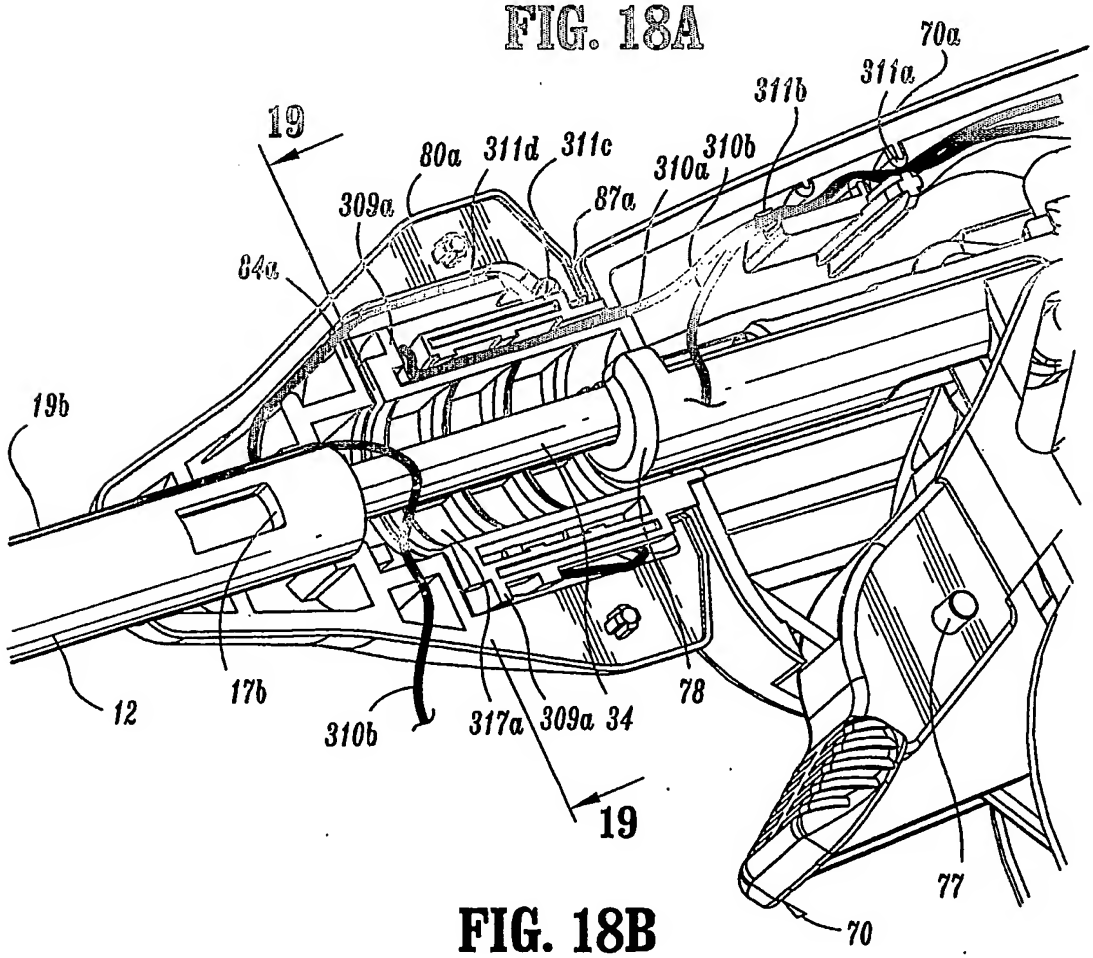

FIG. 18B

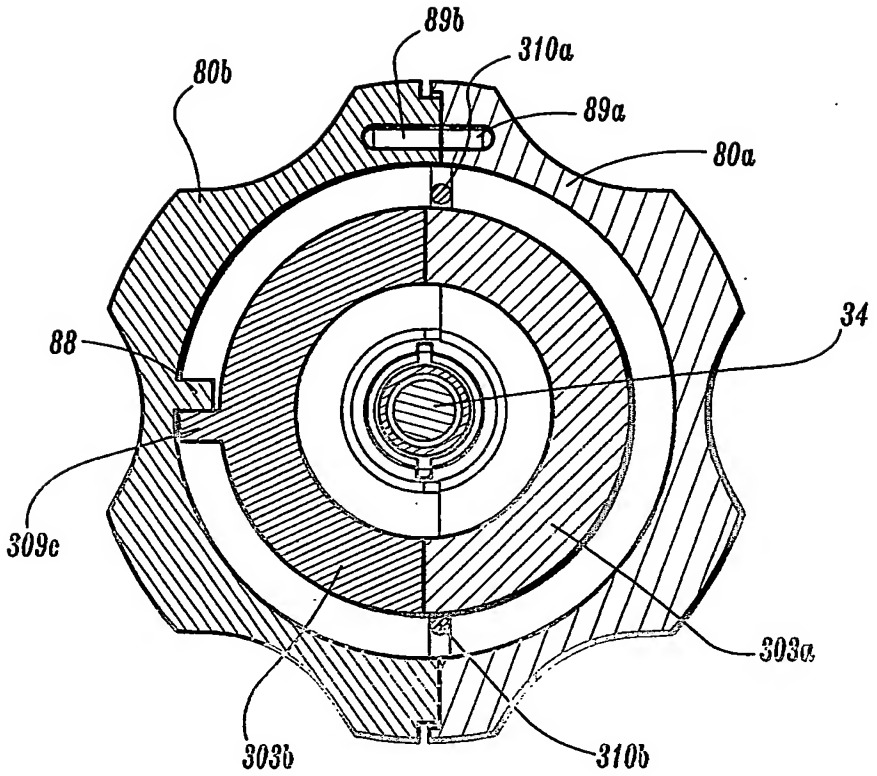

FIG. 19

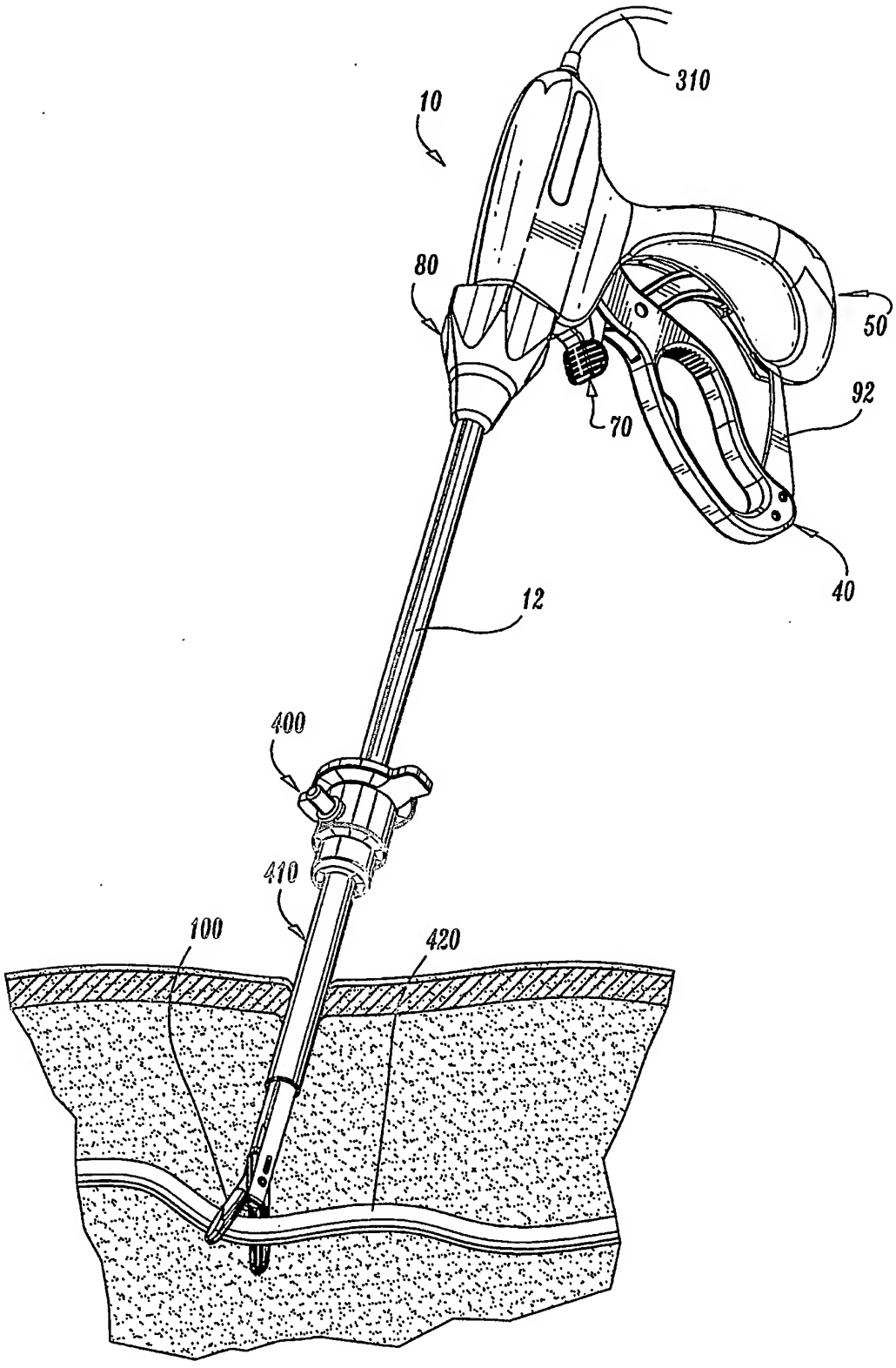

FIG. 20

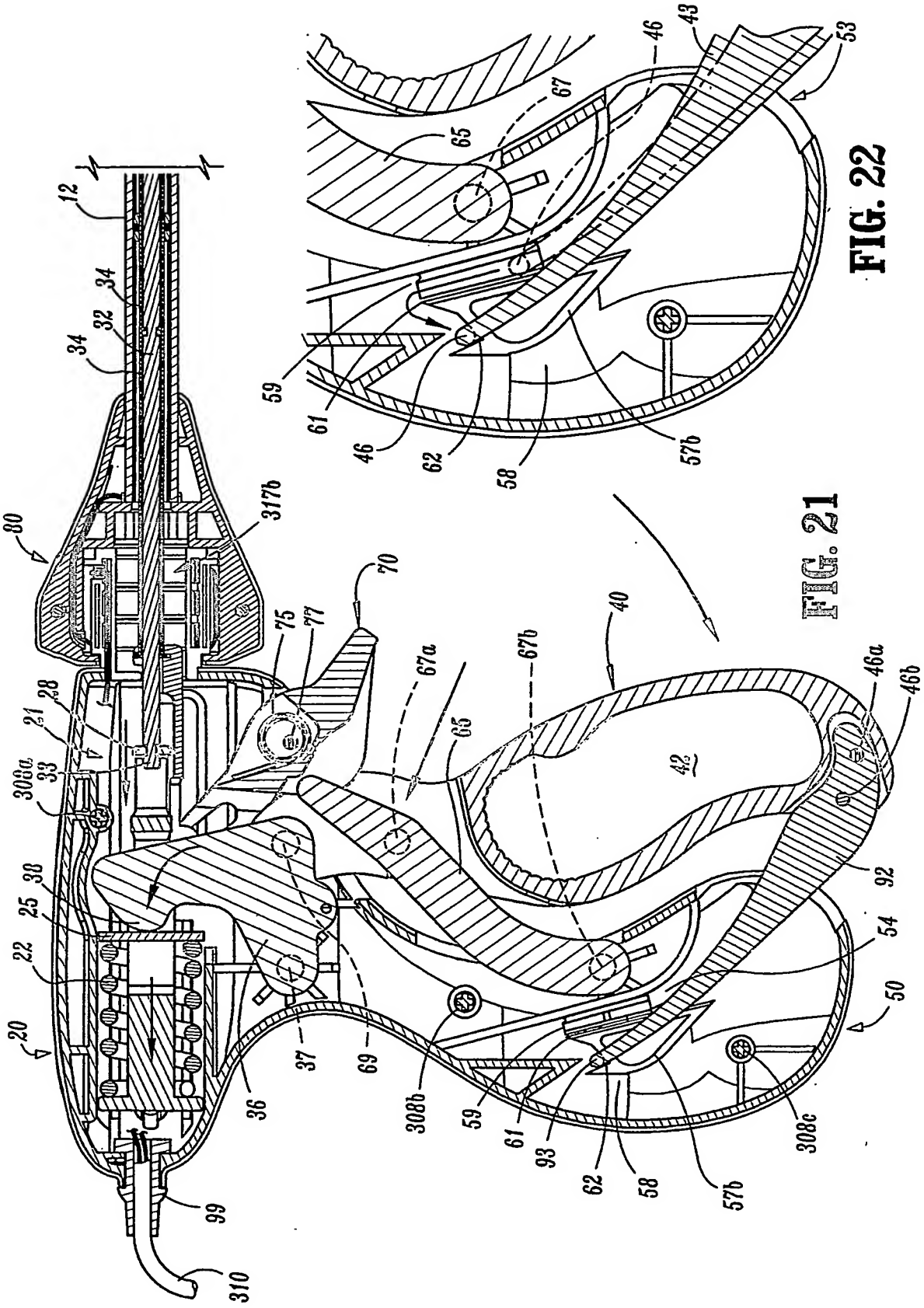
12
34
32
34
80
317b
28
21
308a
33
38
25
22
20
36
37
69
308b
59
61
93
62
58
57b
308c
99
310
70
75
77
67a
65
67b
40
42
46a
46b
92
54
50
53
43
46
67
65
59
61
46
62
58
57b

FIG. 21

FIG. 22

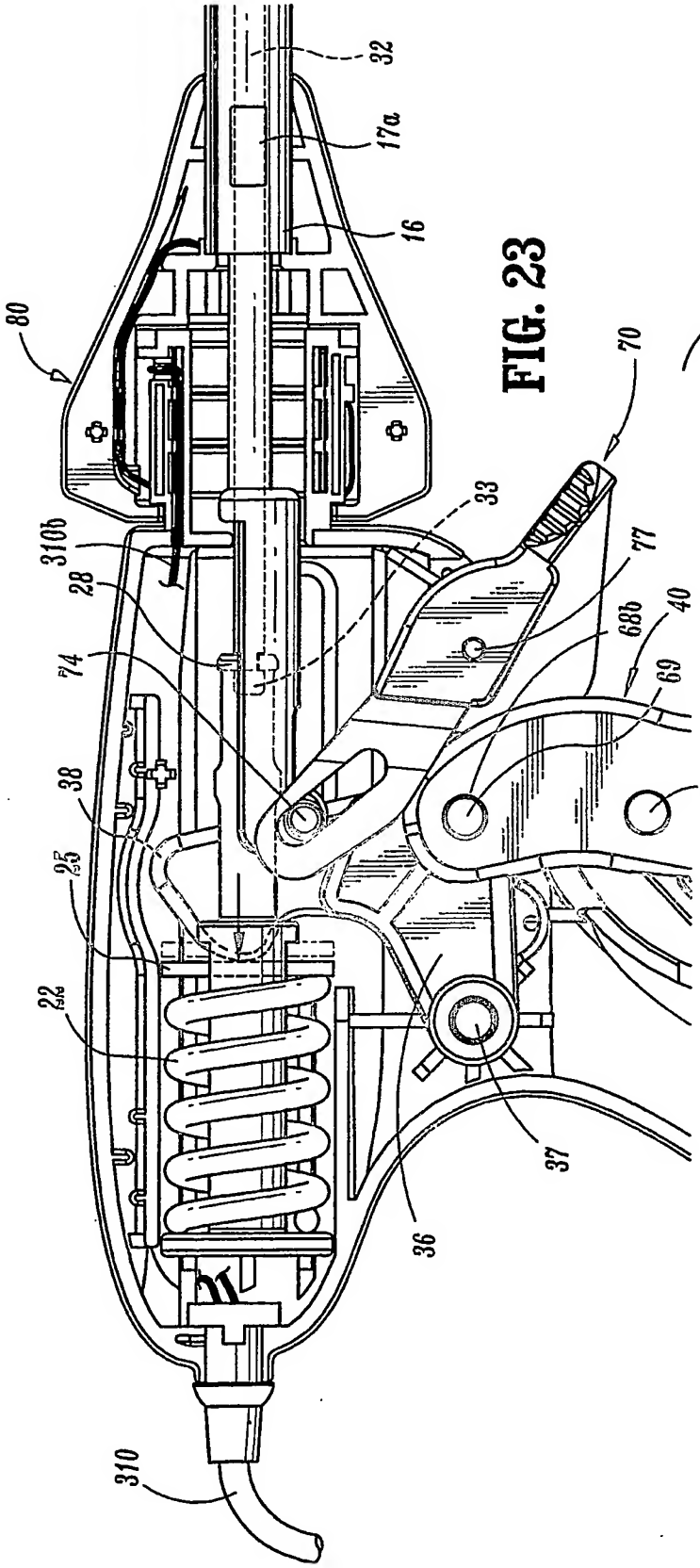
80
32
17a
16
70
33
310b
28
77
74
68b
40
69
38
67a
25
22a
36
37
310

FIG. 23

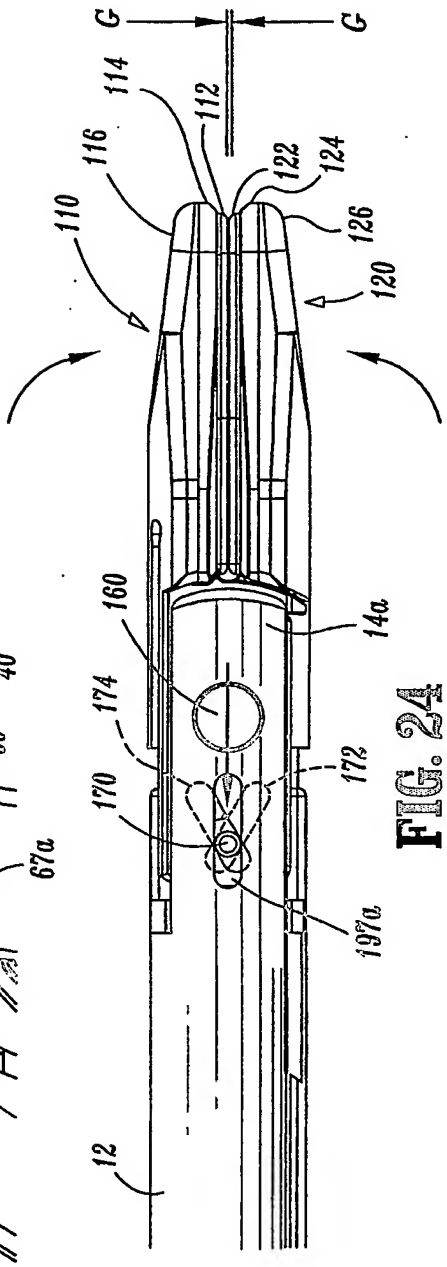
G
G
114
112
116
122
124
110
126
120
160
14a
174
170
172
197a
12

FIG. 24

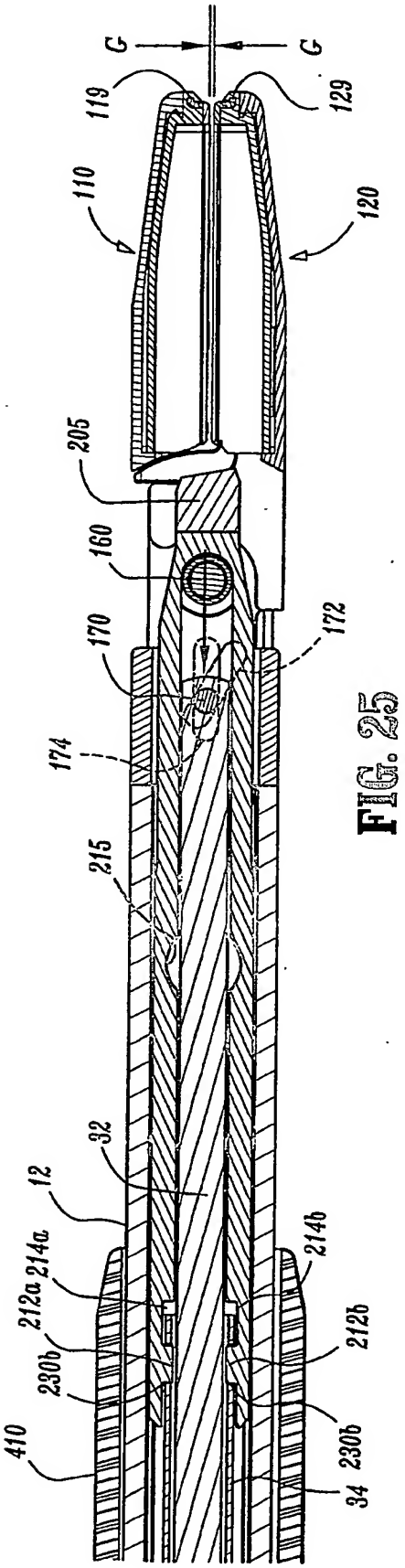
G
G
119
129
110
120
205
160
170
172
174
215
32
12
214a
214b
212a
212b
230b
230b
410
34

FIG. 25

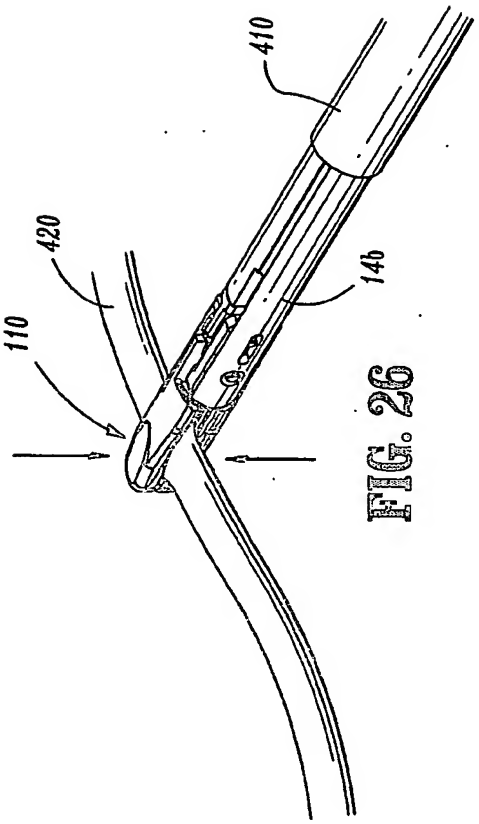
410
420
14b
110

FIG. 26

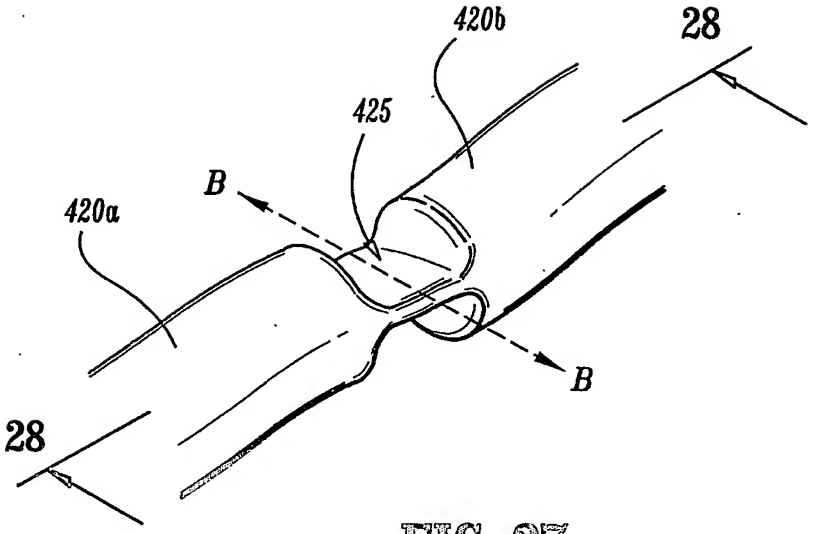

FIG. 27

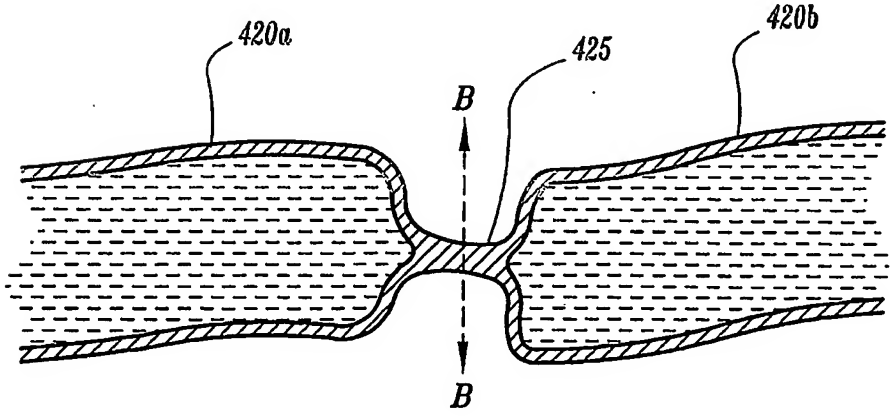

FIG. 28

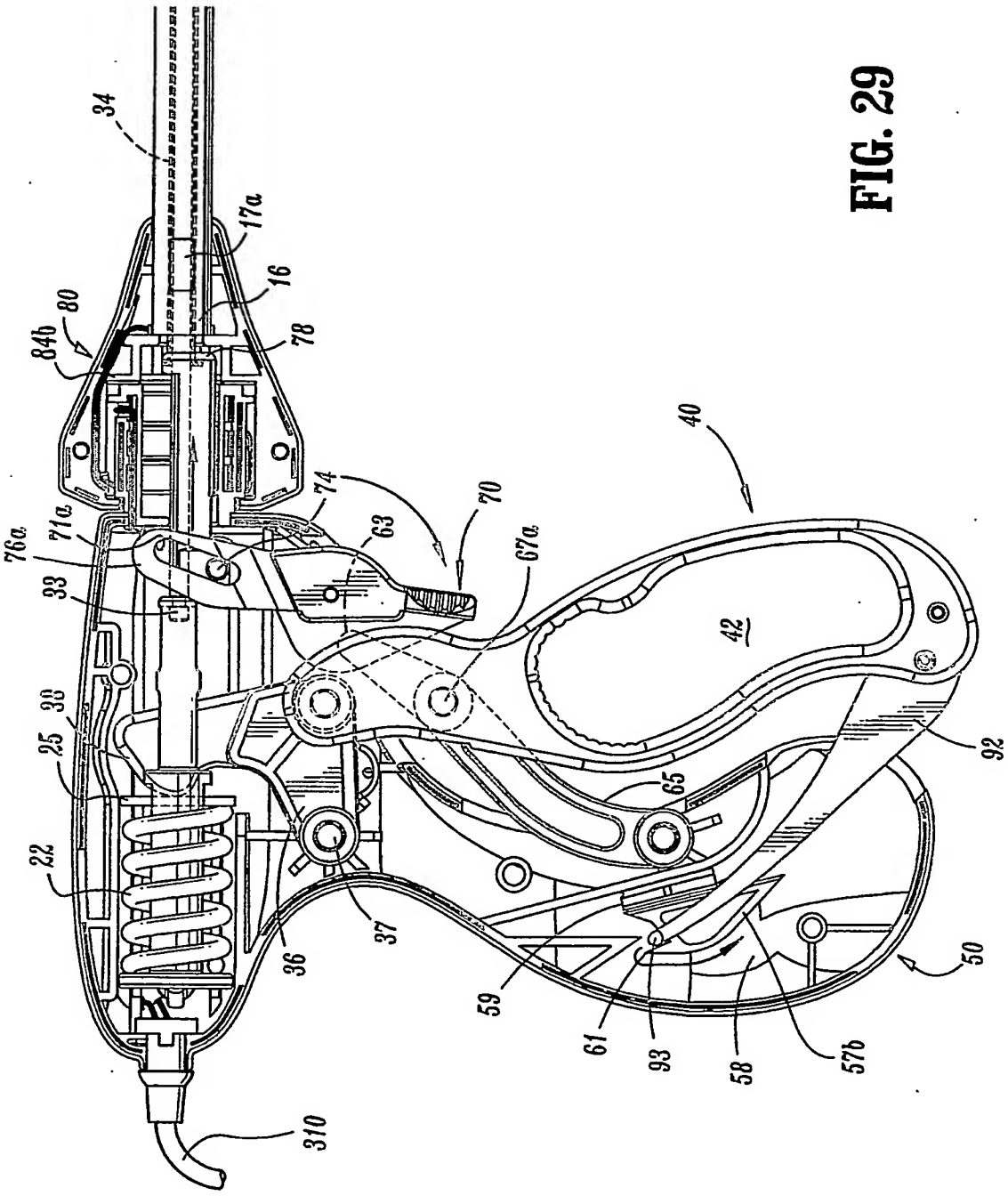
34
17a
16
80
84b
78
40
74
70
63
71a
76a
67a
33
42
30
25
92
65
22
36
37
59
61
93
58
57b
50
310

FIG. 29

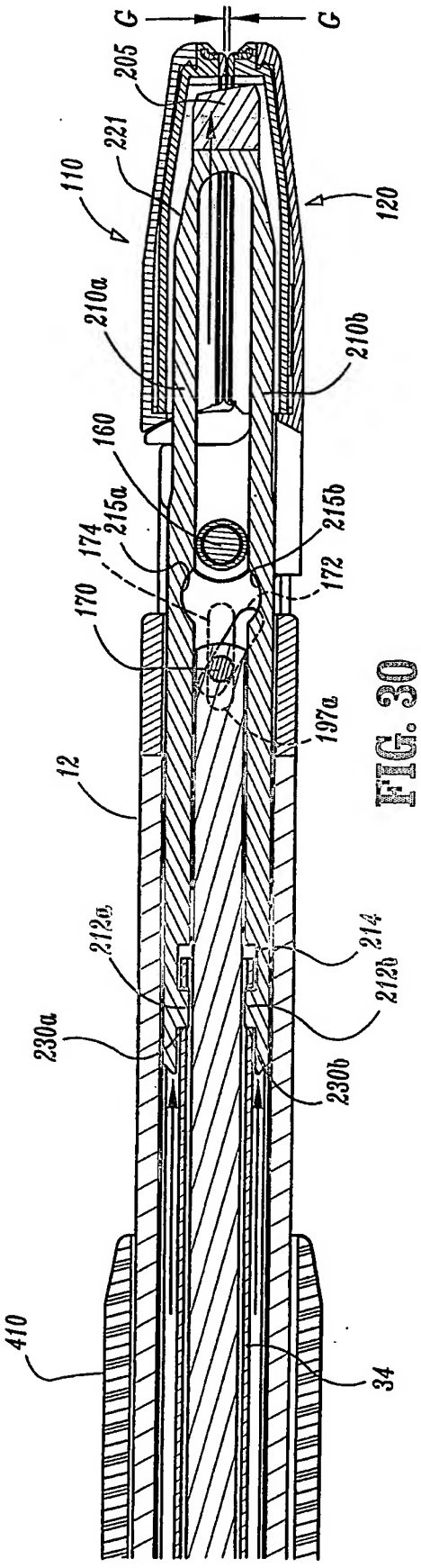
G
G
205
221
110
120
210a
210b
160
215a
215b
174
172
170
197a
12
212a
214
212b
230a
230b
410
34

FIG. 30

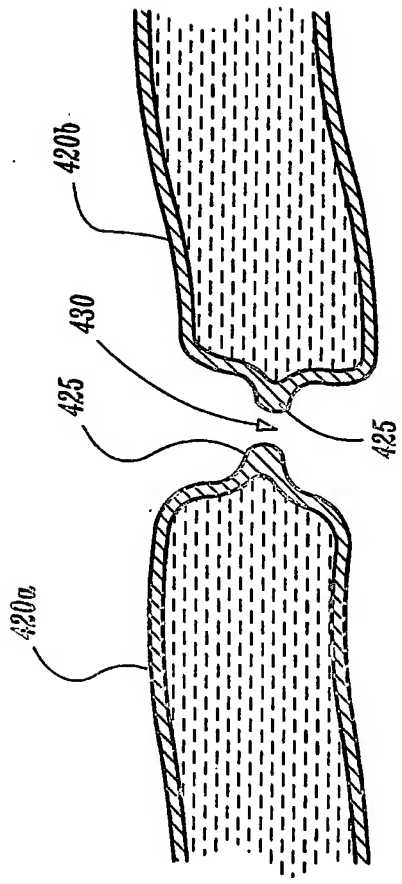
420b
430
425
425
420a

FIG. 31

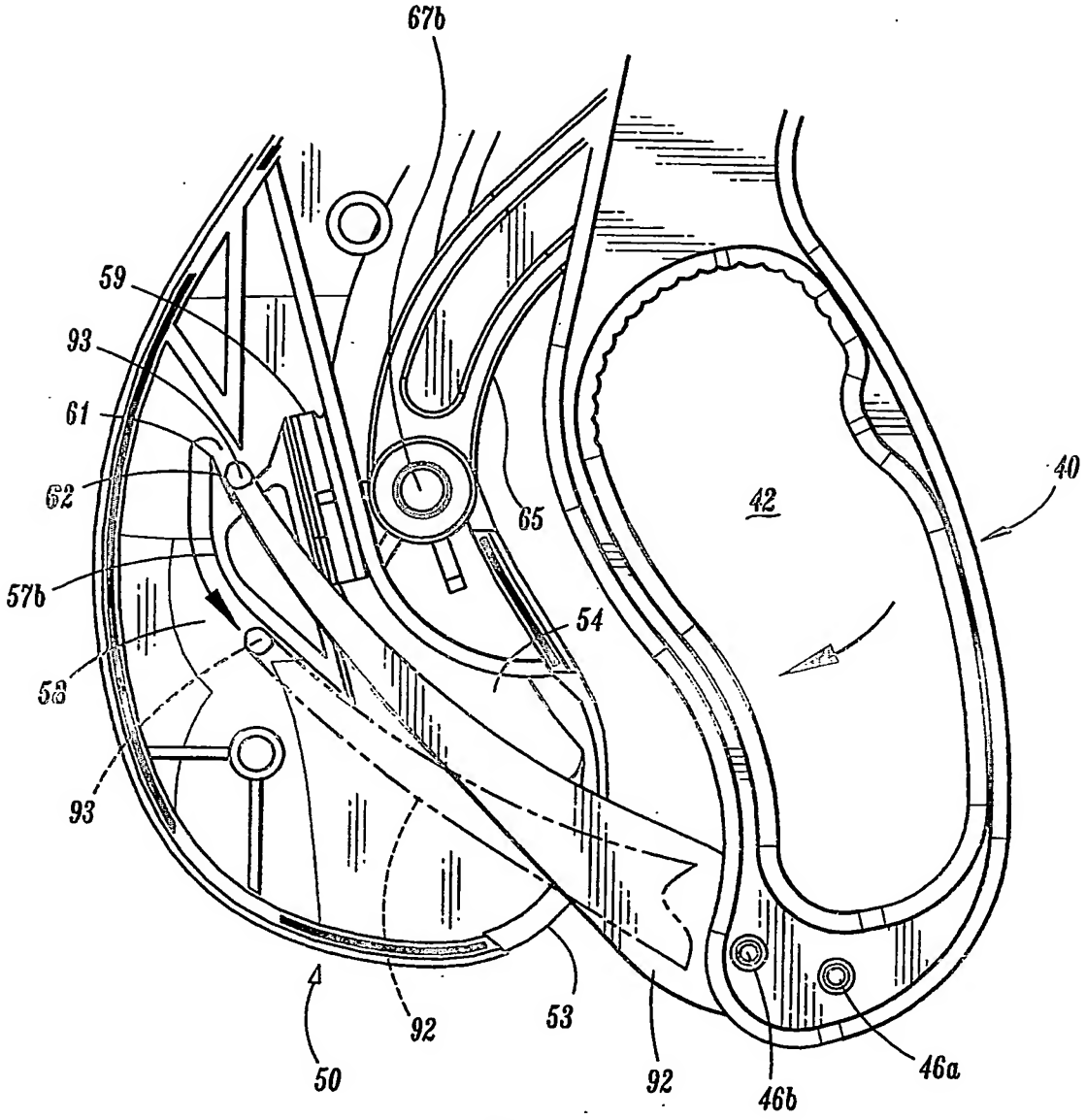

FIG. 32

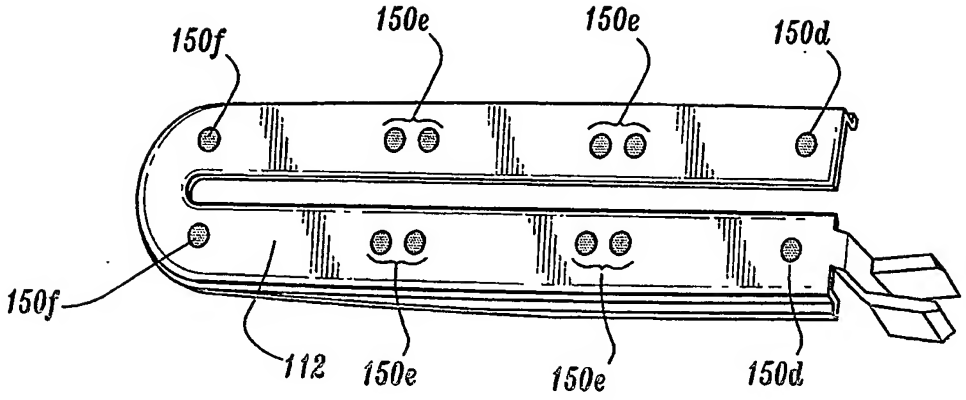

FIG. 33

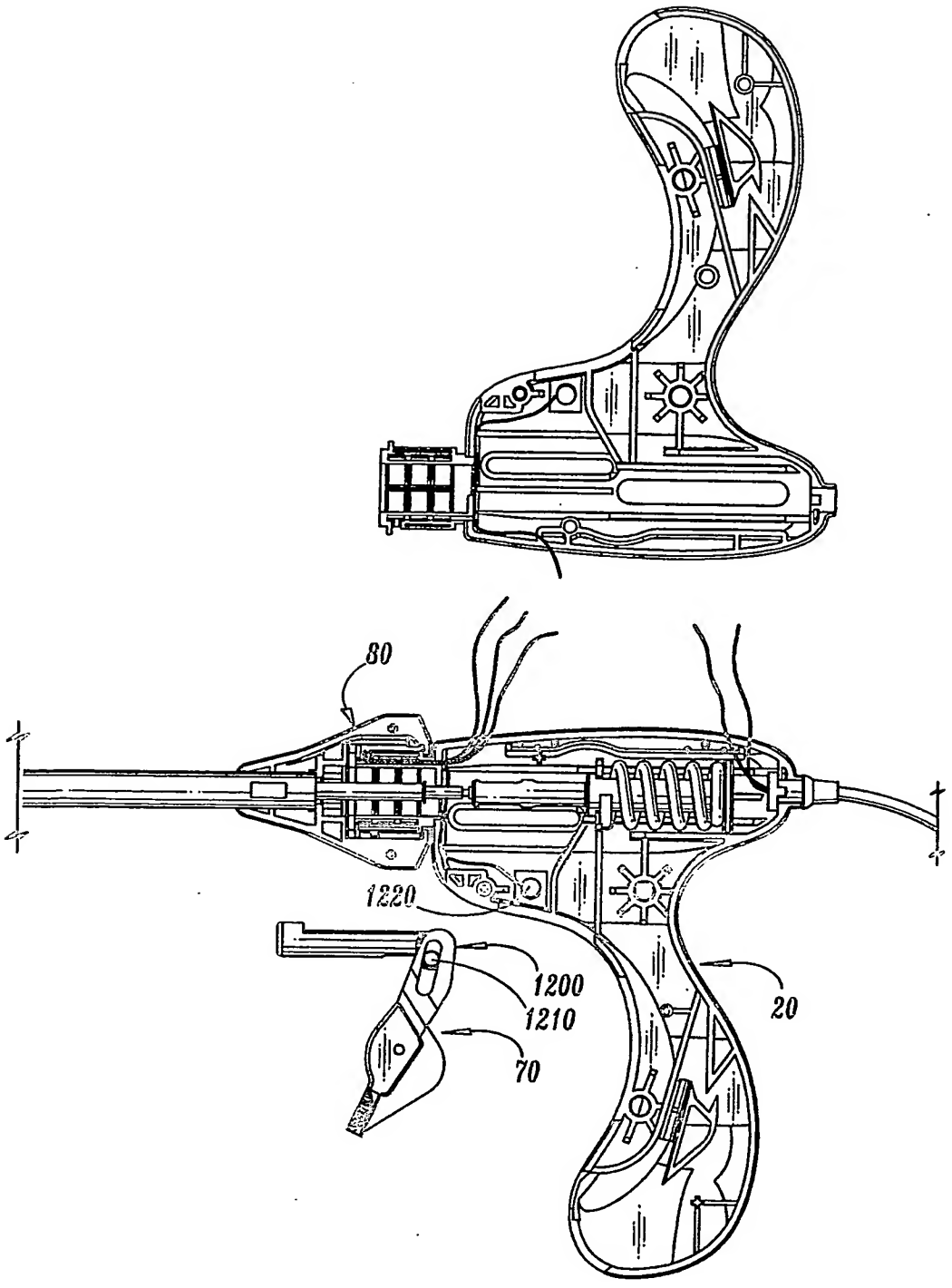

FIG. 34A

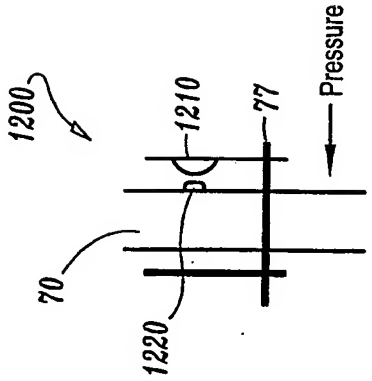

FIG. 34B

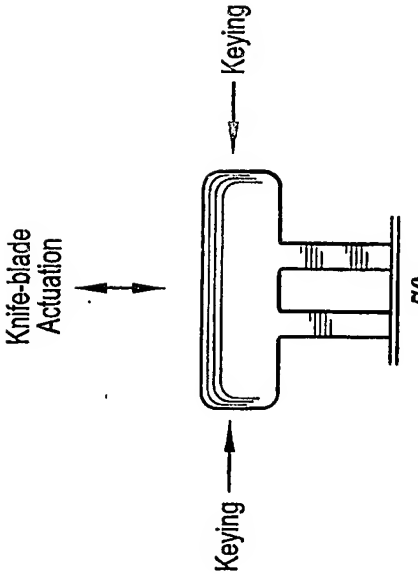

FIG. 34C

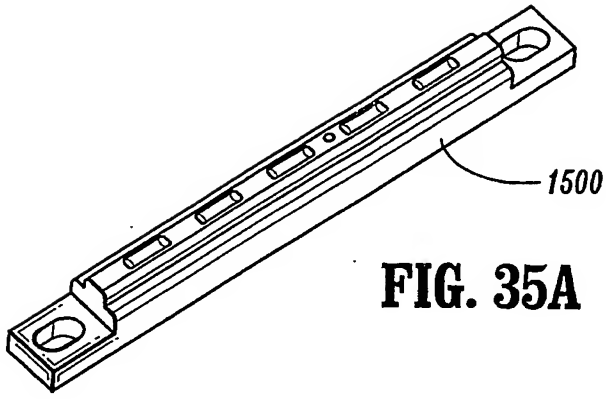

FIG. 35A

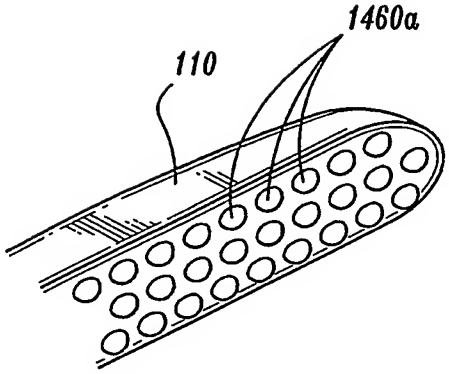

FIG. 35C

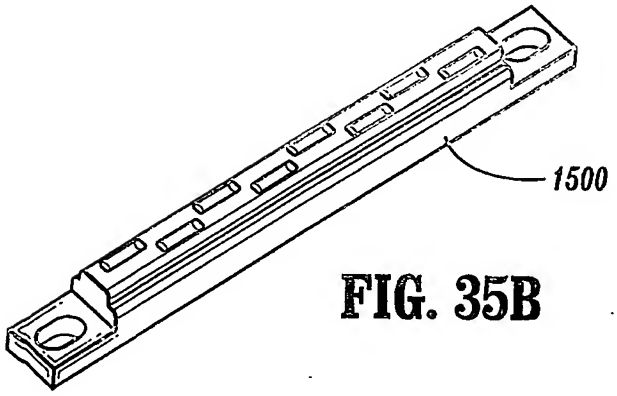

FIG. 35B

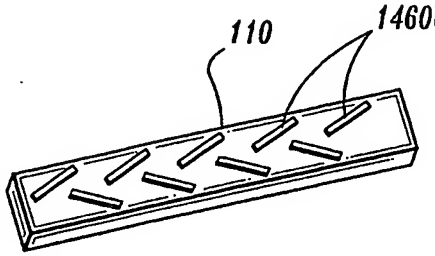

FIG. 35D

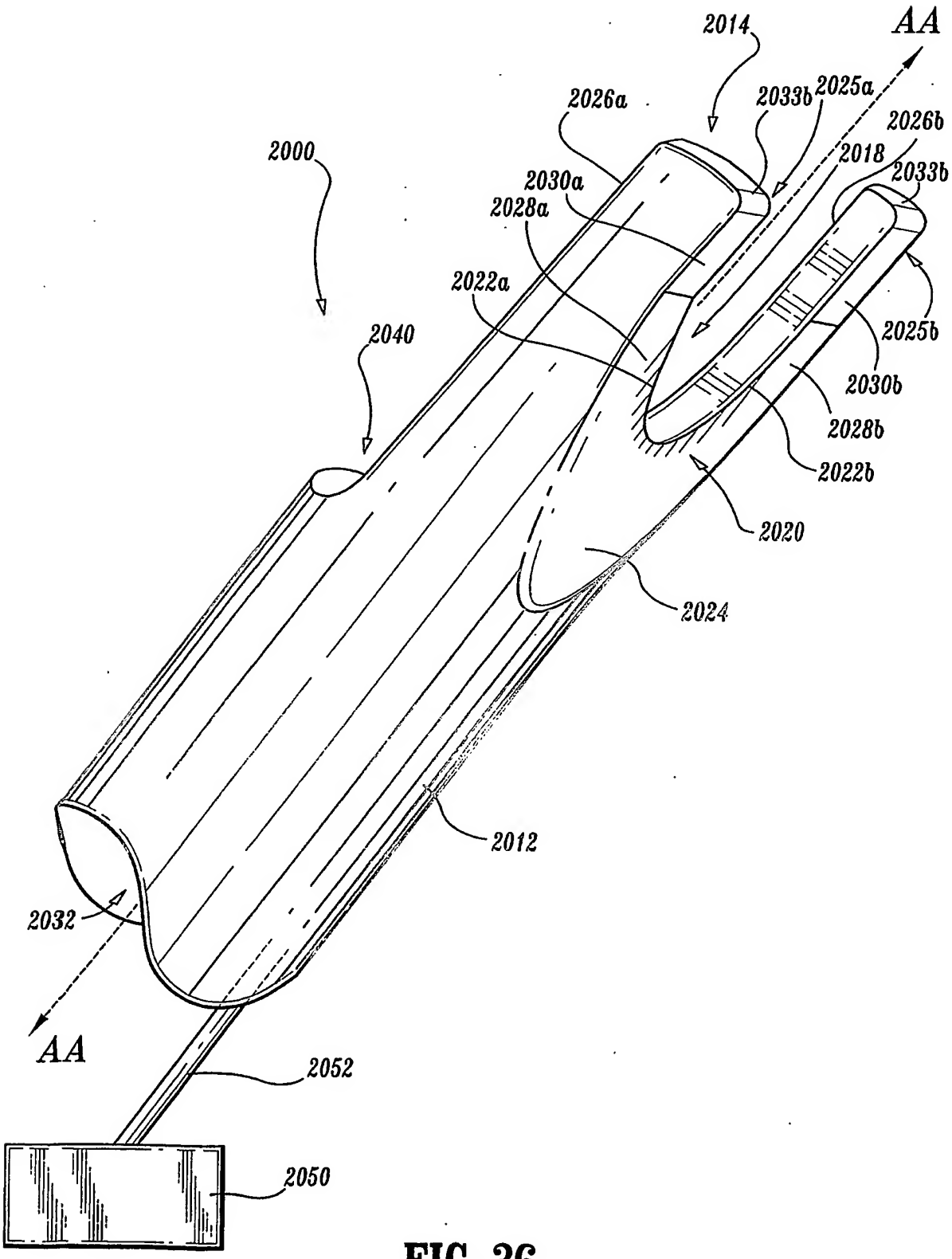
2014
AA
2026a
2033b
2025a
2026b
2000
2018
2033b
2030a
2028a
2022a
2040
2025b
2030b
2028b
2022b
2020
2024
2012
2032
AA
2052
2050

FIG. 36

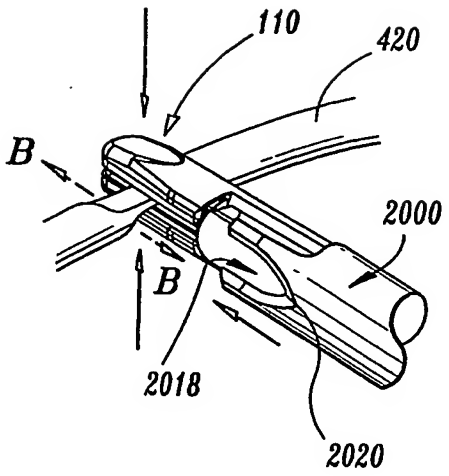

FIG. 37A

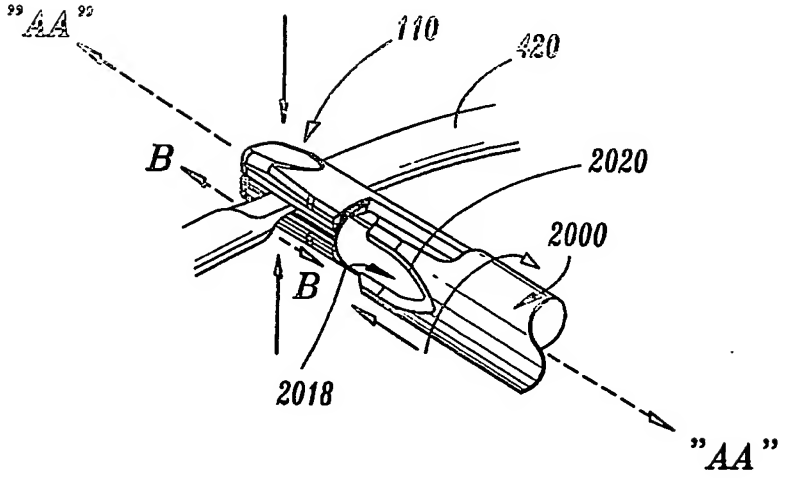

FIG. 37B

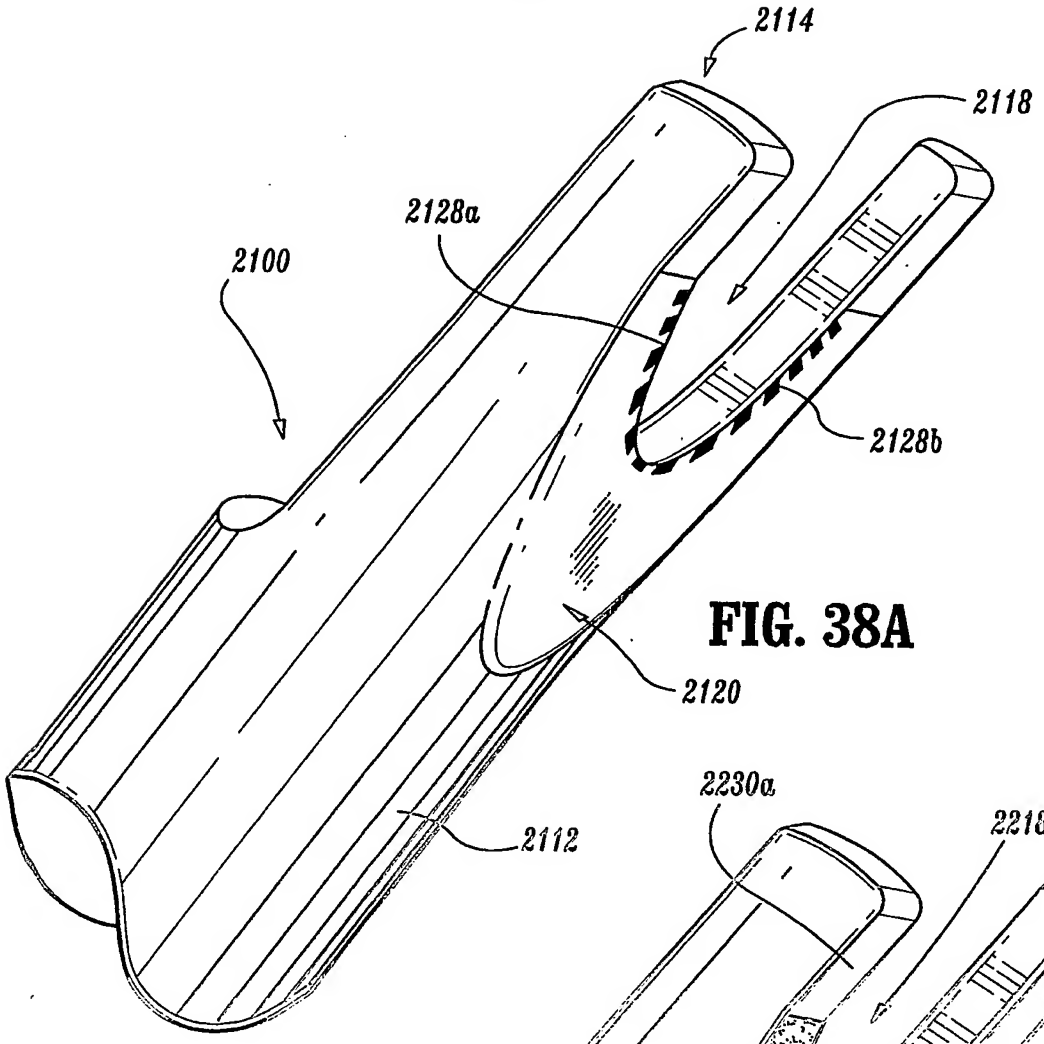

FIG. 38A

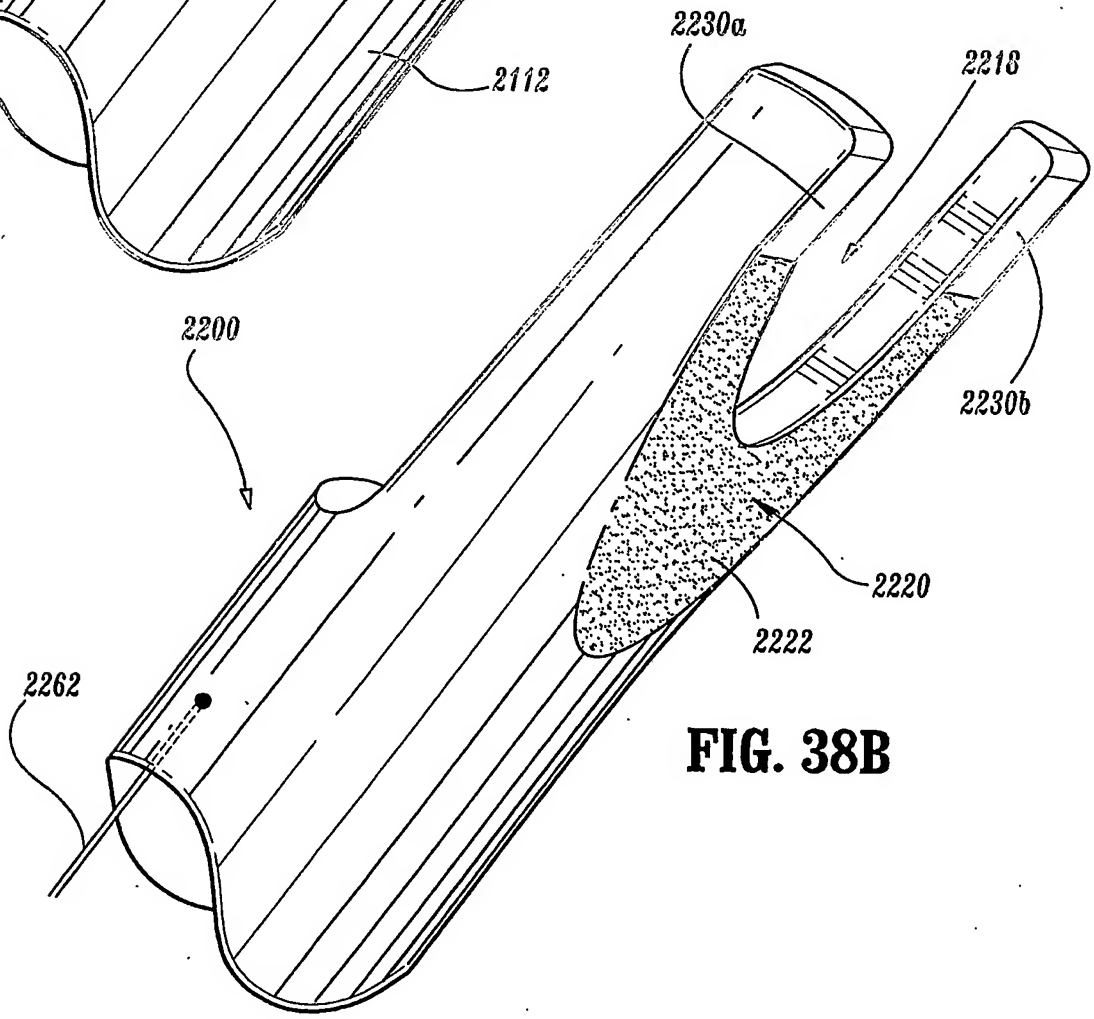

FIG. 38B

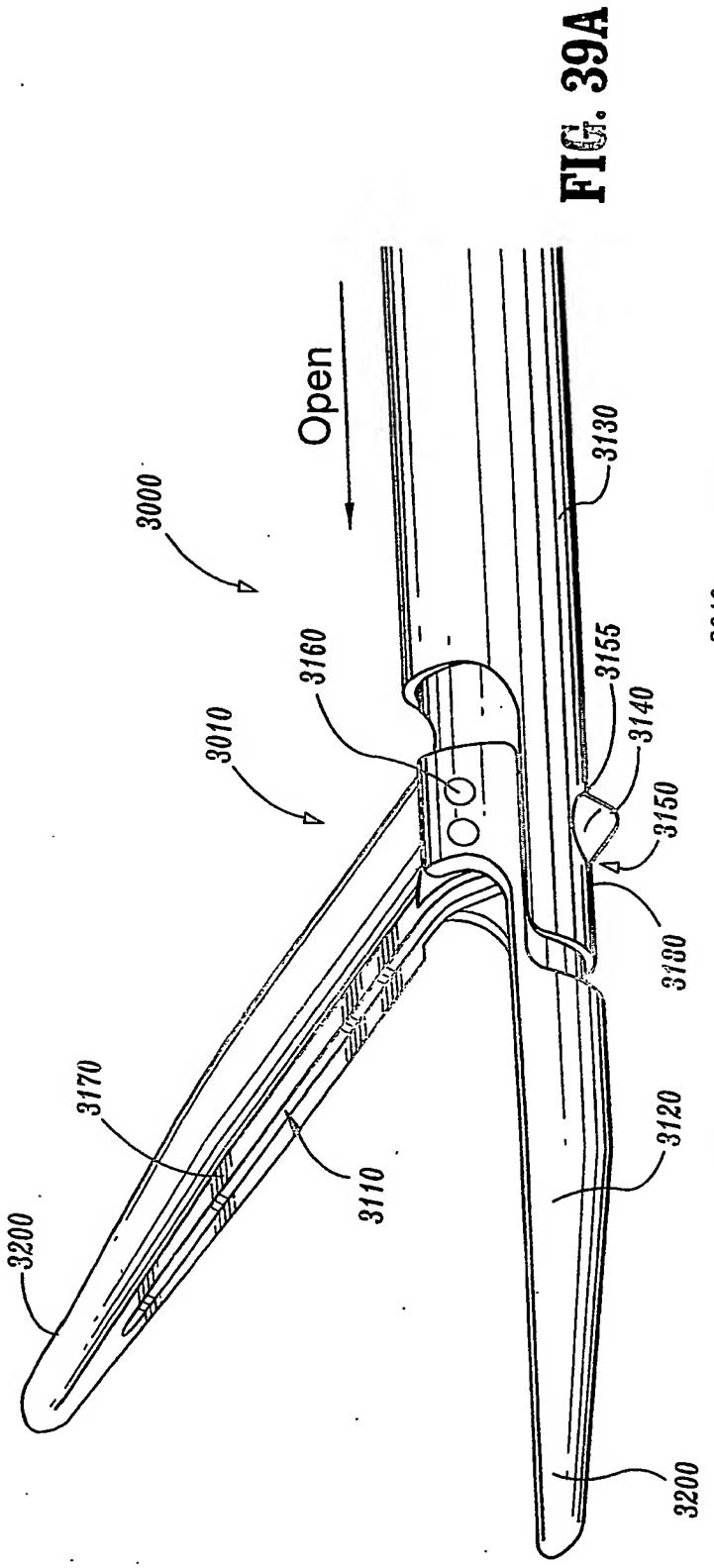

FIG. 39A

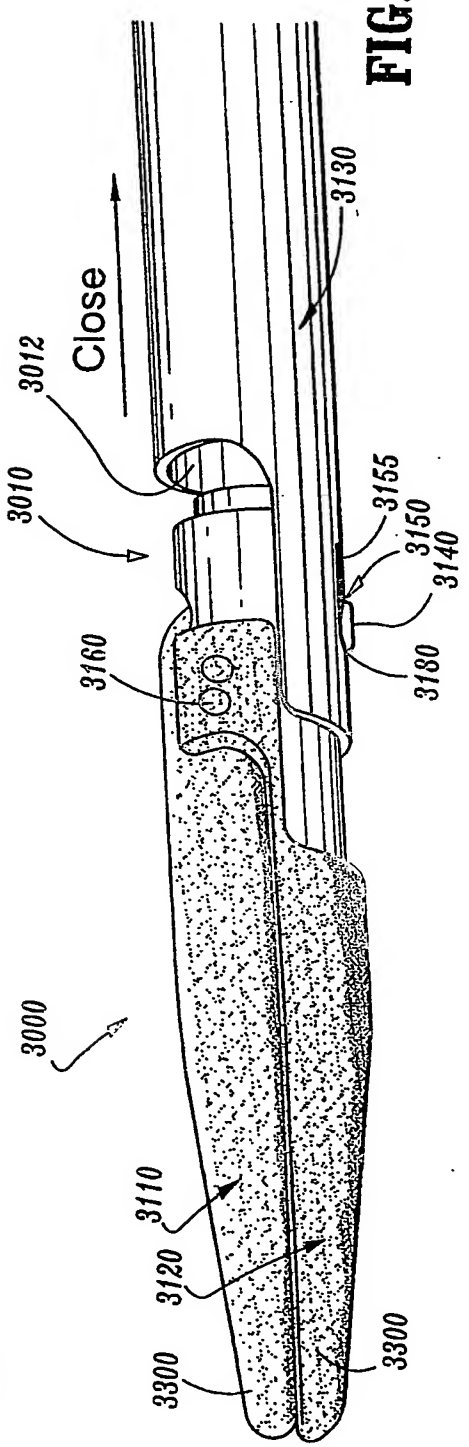

FIG. 39B

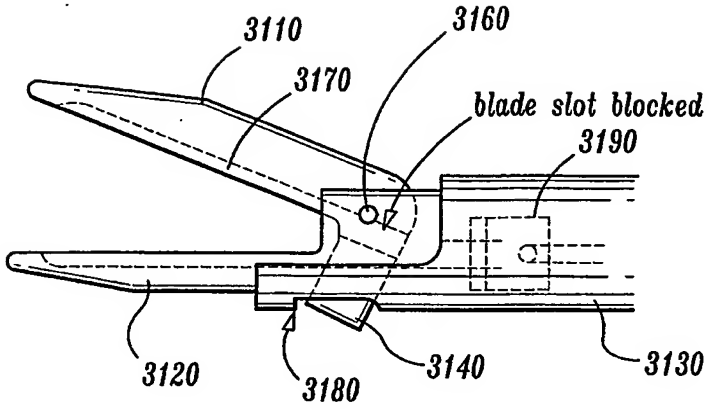

FIG. 39C

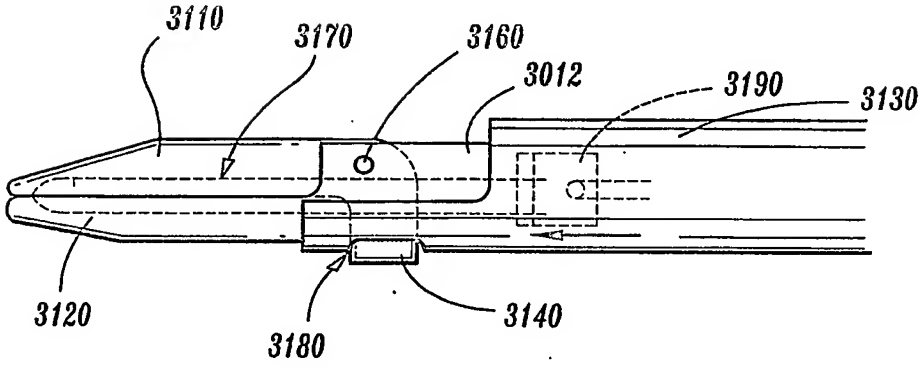

FIG. 39D

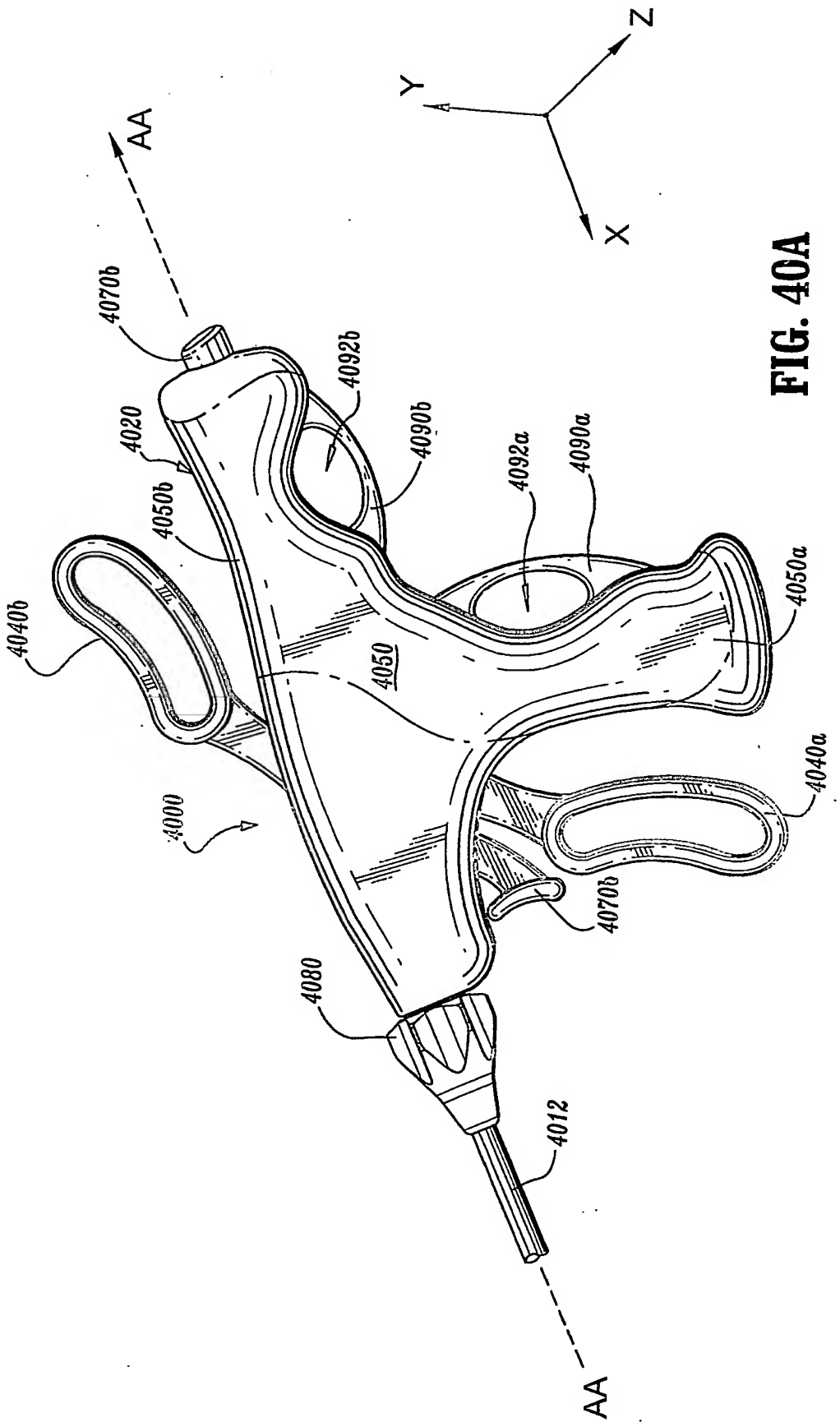
Z
Y
X
AA
4070b
4092b
4020
4090b
4050b
4092a
4090a
4040b
4050a
4050
4040a
4000
4070b
4080
4012
AA

FIG. 40A

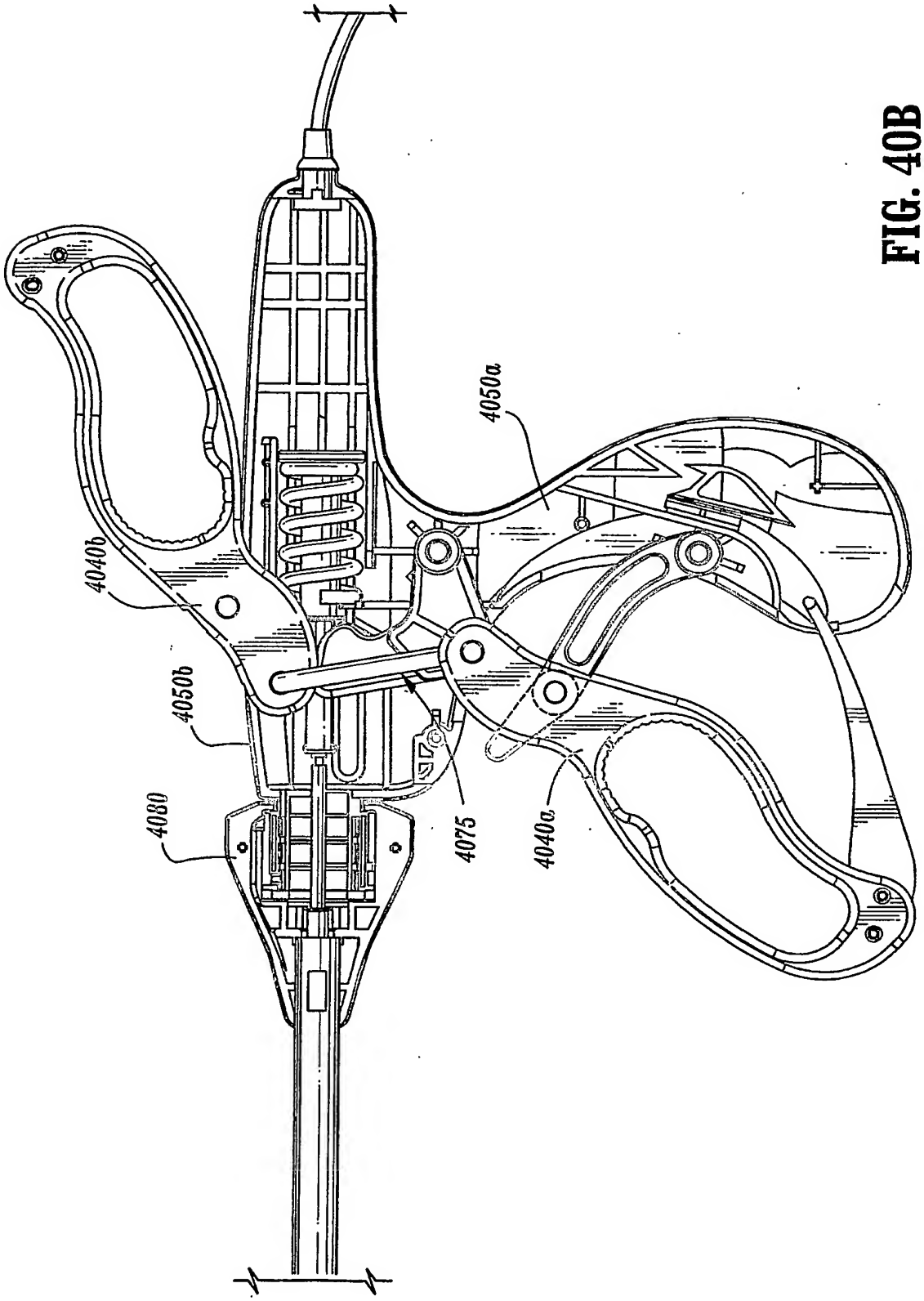

FIG. 40B

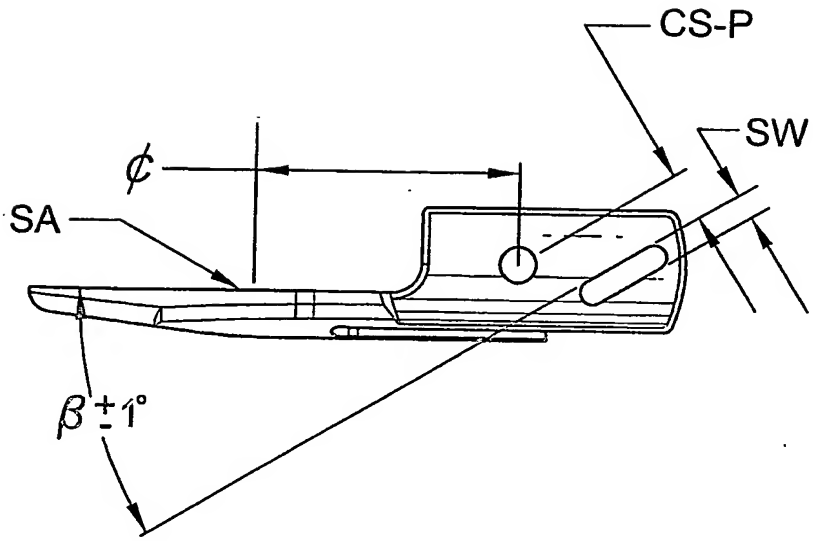

FIG. 41